

# **Dermira Inc**

# **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

A comprehensive coverage of the the company's drug pipeline portfolio including detailed product records.

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## **THOMSON REUTERS**

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## ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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## **GLOSSARY**

## **Number of Drugs in Active Development**

Number of drugs associated with the company or subsidiary that are currently in active development, i.e. the development status for the drug(s) is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

## **Number of Inactive Drugs**

Number of drugs associated with the company or subsidiary that are currently classified as inactive, i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

#### **Number of Patents as Owner**

Number of patents associated with the company where the company is listed as owner; i.e. the relationship type (or way the patent refers to the company) is: Patent Assignee/Owner, Patent owner (not assignee), Licensee for development and marketing, Licensee – marketing only (Distributor), Patent assignee of family member, Inferred assignee.

## **Number of Patents as Third Party**

Number of patents associated with the company where the company is listed as third party; i.e. the relationship type (or way the patent refers to the company) is: Patent assignee (not owner), Ex-Licensee for development and marketing, Ex-Licensee marketing only (Distributor), Customer of technology, Ex-Customer of technology, Patent opponent or infringer, Affiliate organization of inventor, Owner of underlying technology.

#### Patents summary table

This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

#### **Number of Deals**

A count of deals where the company or one of its subsidiaries is the primary company.

#### **Key Indications**

Displays top ten key indications for the company and its subsidiaries based on frequency (indications occurring with high and identical frequency are always included, and this may result in more than ten Key Indications being listed). Includes both indications associated with patents where the company is patent owner and indications associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

## **Key Target-based Actions**

Displays top ten key target-based actions for the company and its subsidiaries based on frequency (actions occurring with high and identical frequency are always included, and this may result in more than ten Key Target-based Actions being listed). Includes both target-based actions associated with patents where the company patent owner and target-based actions associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended. A target-based action is one that is associated with a target.

#### **Key Technologies**

Displays top ten key technologies for the company and its subsidiaries based on frequency (technologies occurring with high and identical frequency are always included, and this may result in more than ten Key Technologies being listed). Includes both key technologies associated with patents where the company relationship is patent owner and key technologies associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

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## **Dermira Inc**

## **COMPANY OVERVIEW**

| Company Name                             | Dermira Inc  |
|--|--|
| Parent Company Name                      | Dermira Inc  |
| Website                                  | http://www.dermira.com/  |
| Country                                  | US   |
| Number of Drugs in Active<br>Development | 5  |
| Number of Inactive Drugs                 | 2  |
| Number of Patents as Owner               | 3  |
| Number of Patents as Third Party         | 1  |
| Number of Deals                          | 1  |
| Key Indications                          | Acne,Psoriasis,Hyperhidrosis,Sebaceous gland disease,Acne vulgaris,Atopic dermatitis,Rosacea,Angina,Brain infarction,Cardiac failure,Coronary artery disease,End stage renal disease,Hearing disorder,Heart disease,Hypertension,Myocardial disease,Neurodegenerative disease,Parkinsons disease,Peripheral vascular disease,Pigment |
| Key Target-based Actions                 | Acetylcholine receptor antagonist,5-Lipoxygenase activating protein inhibitor,5-Lipoxygenase inhibitor,Muscarinic receptor antagonist  |
| Key Technologies                         | Dermatological formulation, Small molecule therapeutic, Crystalline form, Formulation preservation   |

## **COMPANY PROFILE**

#### **SUMMARY**

Dermira was established in late 2010 and is focused on the development and commercialization of innovative therapeutics for dermatological disorders.

#### **ACQUISITIONS & SPIN-OFFS**

In October 2011, the company acquired Valocor Therapeutics.

## **FINANCIAL**

In December 2014, the company was added to the Russell 2000 Index.

In October 2014, the company was to sell 468,750 shares of its common stock, at a price of \$16 each, through a private placement to UCB SA. In October 2014, the company raised approximately \$120.3 million that included proceeds from the IPO and the private placement.

In October 2014, the company priced its initial public offering of 7,812,500 shares of common stock at a price of \$16 each and granted the underwriters a 30-day option to purchase up to an additional 1,171,875 shares. At that time, the shares began trading on the NASDAQ Global Market under the symbol "DERM". Later that month, the offering was completed. At that time, the company raised approximately \$120.3 million that included proceeds from the IPO and the private placement.

In August 2014, the company raised \$51 million in a series C financing.

In June 2013, Dermira raised \$35 million in a series B financing and related transaction.

In October 2011, the company secured \$42 million in a series A financing round.

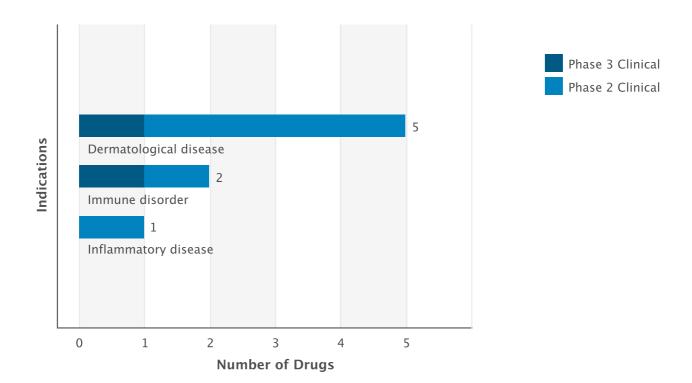
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# PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

# Drugs by Indication

Active Drugs by Indication Chart



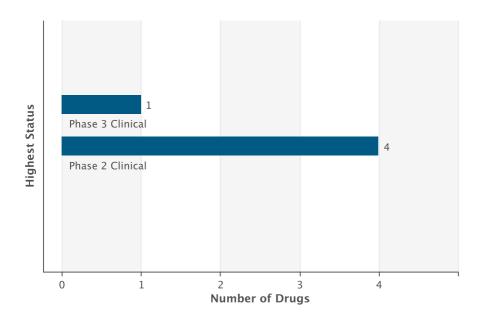
## Drugs by Indication Table

| Indication             | Active | Inactive | Total |
|------------------------|--------|----------|-------|
| Dermatological disease | 5      | 2        | 7     |
| Immune disorder        | 2      | 1        | 3     |
| Inflammatory disease   | 1      | 0        | 1     |

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# **Drugs by Highest Status**

Active Drugs by Highest Status Chart



# Drugs by Highest Status Table

| Development Status      | Number of Drugs |
|-------------------------|-----------------|
| Phase 3 Clinical        | 1               |
| Phase 2 Clinical        | 4               |
| No Development Reported | 2               |

## **DEALS**

| Deal Type                                    | Principal |          | Par    | tner     | Total |
|--|-----------|----------|--------|----------|-------|
|  | Active    | Inactive | Active | Inactive |       |
| Drug - Development/Commercialization License | 0         | 0        | 1      | 0        | 1     |

## **CLINICAL TRIALS**

# Trials by Condition Studied

| Condition Studied      | Ongoing | All |
|------------------------|---------|-----|
| Dermatological disease | 1       | 8   |
| Immune disorder        | 1       | 3   |
| Inflammatory disease   | 0       | 1   |



## Trials by Phase

| Phase   | Ongoing | All |
|---------|---------|-----|
| Phase 3 | 1       | 1   |
| Phase 2 | 0       | 7   |
| Phase 1 | 0       | 1   |

## **Phase Definitions**

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

## Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

#### **PATENTS** \*

| Indication                     | As Owner | As Third Party | Total |
|--------------------------------|----------|----------------|-------|
| Cardiovascular disease         | 0        | 1              | 1     |
| Genitourinary disease          | 0        | 1              | 1     |
| Immune disorder                | 1        | 0              | 1     |
| Metabolic disorder             | 1        | 0              | 1     |
| Neurological disease           | 1        | 1              | 2     |
| Otorhinolaryngological disease | 1        | 0              | 1     |
| Dermatological disease         | 3        | 0              | 3     |

<sup>\*</sup> This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

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## PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

PLEASE NOTE: Highest status refers to highest development of that drug for one of the active companies

## certolizumab pegol

## certolizumab pegol SNAPSHOT

| Drug Name            | certolizumab pegol  |
|----------------------|---|
| Key Synonyms         | Cimzia;certolizumab pegol   |
| Originator Company   | UCB Celltech  |
| Active Companies     | AstraZeneca plc;Dermira Inc;Orient Europharma;Astellas Pharma Inc;NewBridge Pharmaceuticals Ltd;UCB SA;Laboratorios Farmaceuticos Rovi  |
| Inactive Companies   | UCB Celltech;Otsuka Pharmaceutical Co Ltd;Pfizer Inc;Pharmacia Corp   |
| Highest Status       | Launched  |
| Active Indications   | Rheumatoid arthritis;Ulcerative colitis;Psoriatic arthritis;Psoriasis;Juvenile rheumatoid arthritis;Ankylosing spondylitis;Spondylarthritis;Crohns disease                          |
| Target-based Actions | TNF alpha ligand inhibitor;TNF antagonist   |
| Other Actions        | Anti-inflammatory;TNF binding agent;Systemic antipsoriatic product  |
| Technologies         | PEGylated formulation;Biological therapeutic;Subcutaneous formulation;Solution;Freeze drying;Protein recombinant;Monoclonal antibody humanized;Antibody fragment;Protein conjugated |
| Last Change Date     | 18-Jan-2015   |

#### certolizumab pegol DEVELOPMENT PROFILE

#### **SUMMARY**

UCB SA (formerly Celltech) and Japanese licensee Astellas has developed and launched certolizumab pegol (Cimzia; CDP-870), a recombinant PEGylated anti-TNF-alpha humanized monoclonal antibody fragment for sc administration. The product is indicated in the US for reducing the signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adults with moderately to severely active disease who have had an adequate response to conventional therapy. Certolizumab pegol is also indicated in the US for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis and ankylosing spondylitis (AS); in the EU for the treatment of adult patients with severe active axial spondyloarthritis (SpA) and adults with severe active AS, including adults without radiographic evidence of AS, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs); and in the EU in combination with methotrexate (MTX) for the treatment of moderate to severe active RA in adults inadequately responsive to disease-modifying antirheumatic drugs (DMARDs), including MTX and in combination with MTX, for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. The product is indicated in Japan for adults with RA who have had an inadequate response to conventional treatment (including inhibition of progression of bone structural damage).

In January 2008, certolizumab pegol was first launched for CD in Switzerland. Certolizumab pegol was launched for CD in the US in April 2008. By March 2010, UCB had concluded that certolizumab pegol would not be approvable in Europe for CD. In May 2009, a prefilled syringe formulation was launched in the US for the treatment of CD.



US launch for RA took place during May 2009; the product was launched for this indication as a prefilled syringe formulation, developed by the company's partnership with OXO ,. In October 2009, the drug was approved for RA in the EU, and it was launched in Germany and the UK the same month. In February 2012, a phase III trial began in patients with early active moderate-to-severe DMARD-naiive RA. In March 2013, certolizumab pegol was launched in Japan for RA; by September 2013, certolizumab was in phase III in Japan for RA patients not previously treated with conventional therapy, including MTX. In June 2014, the drug was filed for Japasnese approval for treatment-naive or DMARD-naive RA that is predicted to have a rapid structural disease progression,.

In September 2014, certolizumab pegol was launched in the US for the treatment of adults with active psoriatic arthritis. In October 2013, the drug was launched in EU for severe active psoriatic arthritis.

In October 2013, certolizumab pegol was launched in the US for the treatment of adults with active AS. In the same month, the drug was launched in the EU for axial SpA. In February 2013, UCB filed for US approval of the drug for axial SpA. In July 2013, the FDA's Arthritis Advisory Committee recommended approval; the committee concluded that data demonstrated benefit in patients with axial SpA, including AS, and that the safety profile was sufficient to support approval. In October 2013, the FDA issued a Complete Response Letter regarding the sBLA for axial SpA; UCB would work with the FDA to determine the next steps forward for approval of this indication.

Development in other indications is also ongoing. In October 2010, a phase II trial began in ulcerative colitis (UC). In March 2012, phase III development for juvenile RA began; in July 2014, initial results from phase III development in juvenile iodiopathic arthritis were expected in 1H16. Licensee Dermira began phase III trials in moderate-to-severe chronic plaque psoriasis in January 2015; at that time, topline data were expected in 2017.

Previous licensee Pharmacia (now Pfizer) had also been investigating certolizumab pegol for its potential for the treatment of congestive heart failure; however, no development has been reported for this indication since March 2001, and all rights were returned to Celltech in December 2003. Former Japanese licensee Otsuka Pharmaceutical was previously developing the product, and in June 2009, the company was preparing a filing in Japan for CD; however, in January 2012, Otsuka and UCB terminated their collaboration.

In September 2008, the FDA requested manufacturers of TNF-alpha blockers strengthen warnings advising of the risk of opportunistic fungal infections, as cases of histoplasmosis infection were not being consistently recognized in patients taking these medications. In August 2009, the FDA also requested that labeling for anti-TNF drugs be updated to highlight the increased risk of cancer in pediatric patients; the Agency added that the prescribing information should include reports of psoriasis associated with the drug class.

## certolizumab pegol DEVELOPMENT STATUS

## **CURRENT DEVELOPMENT STATUS**

| Company                                  | Indication             | Country | <b>Development Status</b> | Date        |
|--|------------------------|---------|---------------------------|-------------|
| Astellas Pharma Inc                      | Rheumatoid arthritis   | Japan   | Launched                  | 08-Mar-2013 |
| AstraZeneca plc                          | Crohns disease         | Brazil  | Launched                  | 28-Sep-2009 |
| AstraZeneca plc                          | Rheumatoid arthritis   | Brazil  | Launched                  | 28-Sep-2009 |
| Laboratorios<br>Farmaceuticos Rovi<br>SA | Rheumatoid arthritis   | Spain   | Launched                  | 31-Dec-2009 |
| UCB SA                                   | Ankylosing spondylitis | Canada  | Launched                  | 31-Dec-2013 |



| Company | Indication             | Country               | <b>Development Status</b> | Date        |
|---------|------------------------|-----------------------|---------------------------|-------------|
| UCB SA  | Ankylosing spondylitis | US                    | Launched                  | 31-Oct-2013 |
| UCB SA  | Crohns disease         | Switzerland           | Launched                  | 31-Jan-2008 |
| UCB SA  | Crohns disease         | US                    | Launched                  | 24-Apr-2008 |
| UCB SA  | Psoriatic arthritis    | EU                    | Launched                  | 31-Oct-2013 |
| UCB SA  | Psoriatic arthritis    | US                    | Launched                  | 30-Sep-2013 |
| UCB SA  | Rheumatoid arthritis   | Australia             | Launched                  | 12-Jan-2011 |
| UCB SA  | Rheumatoid arthritis   | Canada                | Launched                  | 01-Sep-2009 |
| UCB SA  | Rheumatoid arthritis   | Czech<br>Republic     | Launched                  |             |
| UCB SA  | Rheumatoid arthritis   | Denmark               | Launched                  | 16-Nov-2009 |
| UCB SA  | Rheumatoid arthritis   | EU                    | Launched                  | 02-Mar-2010 |
| UCB SA  | Rheumatoid arthritis   | France                | Launched                  | 04-Jan-2010 |
| UCB SA  | Rheumatoid arthritis   | Germany               | Launched                  | 26-Oct-2009 |
| UCB SA  | Rheumatoid arthritis   | Greece                | Launched                  |             |
| UCB SA  | Rheumatoid arthritis   | Japan                 | Launched                  | 08-Mar-2013 |
| UCB SA  | Rheumatoid arthritis   | Netherlands           | Launched                  |             |
| UCB SA  | Rheumatoid arthritis   | Norway                | Launched                  | 29-Apr-2010 |
| UCB SA  | Rheumatoid arthritis   | Portugal              | Launched                  | 23-Aug-2012 |
| UCB SA  | Rheumatoid arthritis   | Russian<br>Federation | Launched                  | 27-Oct-2011 |
| UCB SA  | Rheumatoid arthritis   | Slovakia              | Launched                  |             |
| UCB SA  | Rheumatoid arthritis   | Sweden                | Launched                  | 30-Mar-2010 |
| UCB SA  | Rheumatoid arthritis   | Switzerland           | Launched                  | 12-Jan-2011 |
| UCB SA  | Rheumatoid arthritis   | UK                    | Launched                  | 26-Oct-2009 |
| UCB SA  | Rheumatoid arthritis   | US                    | Launched                  | 14-May-2009 |
| UCB SA  | Spondylarthritis       | EU                    | Launched                  | 31-Oct-2013 |
| UCB SA  | Ankylosing spondylitis | Australia             | Registered                | 01-May-2014 |
| UCB SA  | Psoriatic arthritis    | Australia             | Registered                | 01-May-2014 |
| UCB SA  | Rheumatoid arthritis   | Estonia               | Registered                | 01-Oct-2009 |
|         |                        |                       |                           |             |



| Company                          | Indication                    | Country            | <b>Development Status</b> | Date        |
|----------------------------------|-------------------------------|--------------------|---------------------------|-------------|
| UCB SA                           | Rheumatoid arthritis          | Lithuania          | Registered                | 01-Oct-2009 |
| UCB SA                           | Spondylarthritis              | US                 | Pre-registration          | 20-Feb-2013 |
| Dermira Inc                      | Psoriasis                     | US                 | Phase 3 Clinical          | 08-Jan-2015 |
| UCB SA                           | Juvenile rheumatoid arthritis | Belgium            | Phase 3 Clinical          | 31-Mar-2012 |
| UCB SA                           | Psoriatic arthritis           | Argentina          | Phase 3 Clinical          | 15-Mar-2010 |
| UCB SA                           | Psoriatic arthritis           | Canada             | Phase 3 Clinical          | 15-Mar-2010 |
| UCB SA                           | Psoriatic arthritis           | Mexico             | Phase 3 Clinical          | 15-Mar-2010 |
| UCB SA                           | Spondylarthritis              | Canada             | Phase 3 Clinical          | 15-Mar-2010 |
| UCB SA                           | Spondylarthritis              | South America      | Phase 3 Clinical          | 15-Mar-2010 |
| UCB SA                           | Crohns disease                | Japan              | Phase 2 Clinical          | 31-Mar-2006 |
| UCB SA                           | Ulcerative colitis            | US                 | Phase 2 Clinical          | 31-Oct-2010 |
| Dermira Inc                      | Psoriasis                     | Canada             | Discovery                 | 03-Jul-2014 |
| Dermira Inc                      | Psoriasis                     | EU                 | Discovery                 | 03-Jul-2014 |
| NewBridge<br>Pharmaceuticals Ltd | Crohns disease                | Africa             | Discovery                 | 22-Nov-2012 |
| NewBridge<br>Pharmaceuticals Ltd | Crohns disease                | Middle East        | Discovery                 | 22-Nov-2012 |
| NewBridge<br>Pharmaceuticals Ltd | Rheumatoid arthritis          | Africa             | Discovery                 | 22-Nov-2012 |
| NewBridge<br>Pharmaceuticals Ltd | Rheumatoid arthritis          | Middle East        | Discovery                 | 22-Nov-2012 |
| Orient Europharma                | Rheumatoid arthritis          | South East<br>Asia | Discovery                 | 14-Oct-2010 |
| UCB SA                           | Rheumatoid arthritis          | China              | Discovery                 | 31-Dec-2010 |
| Otsuka<br>Pharmaceutical Co Ltd  | Crohns disease                | Japan              | Discontinued              | 13-Jan-2012 |
| Otsuka<br>Pharmaceutical Co Ltd  | Rheumatoid arthritis          | Japan              | Discontinued              | 13-Jan-2012 |
| Otsuka<br>Pharmaceutical Co Ltd  | Rheumatoid arthritis          | South Korea        | Discontinued              | 13-Jan-2012 |
| Pfizer Inc                       | Crohns disease                | US                 | Discontinued              | 01-Dec-2003 |
| Pfizer Inc                       | Rheumatoid arthritis          | US                 | Discontinued              | 01-Dec-2003 |
| UCB Celltech                     | Rheumatoid arthritis          | UK                 | Discontinued              | 18-May-2004 |
| UCB SA                           | Crohns disease                | EU                 | Discontinued              | 21-Mar-2010 |
|                                  |                               |                    |                           |             |



| Company      | Indication      | Country | Development Status      | Date        |
|--------------|-----------------|---------|-------------------------|-------------|
| UCB SA       | Psoriasis       | US      | Discontinued            | 18-Jan-2010 |
| UCB Celltech | Cardiac failure | UK      | No Development Reported | 18-Mar-2003 |

# certolizumab pegol DRUG NAMES

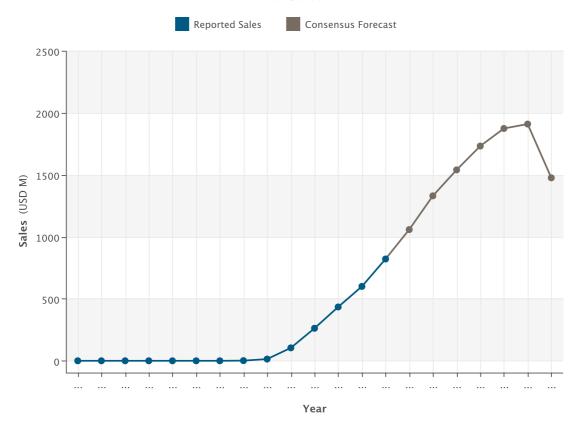
| Names              | Туре          |
|--------------------|---------------|
| certolizumab pegol | INN           |
| Cimzia             | Trade Name    |
| CDP-870            | Research Code |

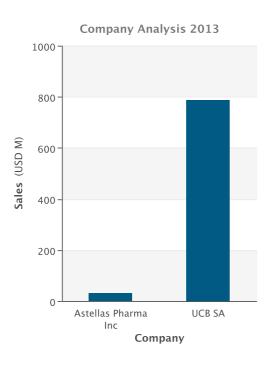
# certolizumab pegol SALES AND FORECASTS

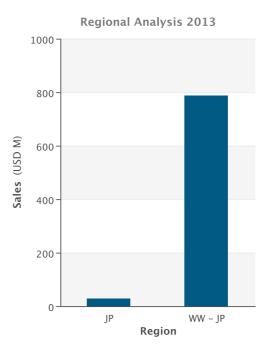
**CHARTS** 



## **Total Sales**









#### **COMMENTARY**

#### **CONSENSUS SALES INFORMATION**

Consensus forecast data for UCB SA and Astellas Pharma are presented. No Consensus forecast data are currently available for AstraZeneca, Laboratorios Farmaceuticos Rovi (ROVI), NewBridge or Dermira, which hold rights in selected regions or for selected indications.

#### **REPORTED ANNUAL SALES**

Sales forcertolizumab pegol (Cimzia) reported by UCB for 2013 were EUR 594.0 million (\$788.8 million), representing a year-on-year increase of 27% on 2012 [1531024]. Sales for certolizumab pegol (Cimzia) reported by Astellas for 2013 were JPY 3.2 billion (\$33.0 million) [1556559].

#### REGIONAL DEVELOPMENT AND MARKETING RIGHTS

In March 2001, Celltech and Pharmacia (now Pfizer) signed a worldwide agreement for the codevelopment and copromotion of certolizumab pegol in Japan, the US and major EU markets. Under the agreement, Celltech was to lead the development and fund the majority of development costs for CD, while Pharmacia managed and funded the majority of development for RA and other indications; Celltech had intended development in both CD and RA [469064]. In November 2003, following delays imposed by Pfizer on development in RA, Celltech intended to file certolizumab pegol for CD only initially. At that time, Pfizer planned to postpone further phase III trials in RA pending the results of ongoing studies and wanted to renegotiate the financial terms of its collaboration with Celltech [513129], [400886], [401949], [401925]. In December 2003, Pfizer gave Celltech 90 days notice of termination of its rights to certolizumab pegol. Following termination, all rights and program information reverted to Celltech [515522].

In May 2004, Celltech granted UCB exclusive worldwide development and marketing rights to certolizumab pegol for a number of indications including RA, while retaining all manufacturing rights and all rights for CD [539295]; UCB subsequently acquired Celltech [548223].

In June 2008, Otsuka acquired copromotion rights from UCB in Japan for CD, and copromotion and codevelopment rights for other indications [915126]. In January 2012, Otsuka and UCB terminated their collaboration [1254712]. Later that month, UCB and Astellas entered into an agreement to jointly develop and commercialize certolizumab pegol for RA in Japan; under the agreement, Astellas books all sales [1259355].

In September 2009, UCB entered into an agreement with AstraZeneca to register and commercialize certolizumab pegol in Brazil [1045369].

In December 2009, ROVI and UCB signed an agreement to commercialize certolizumab pegol in Spain; UCB would complete the local approval procedure, maintain marketing authorization and upon approval, copromote the drug [1064475].

In November 2012, UCB and NewBridge Pharmaceuticals entered an exclusive partnership to make certolizumab available in the Middle East and African regions. UCB was to supply the drug, while NewBridge would be responsible for managing local regulatory approval processes, future commercialization, and pharmacovigilance in each of the relevant countries [1342892].

In July 2014, Dermira licensed the exclusive rights to develop and commercialize the drug for psoriasis in the US, Canada and the EU [1574685].

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# certolizumab pegol CLINICAL TRIALS

## Trials by Phase and Condition Studied

|              | se 4<br>nical |               | se 3<br>nical |              | se 2<br>nical |              | se 1<br>nical | Pha<br>Unspe | ase<br>ecified | То           | tal |
|--------------|---------------|---------------|---------------|--------------|---------------|--------------|---------------|--------------|----------------|--------------|-----|
| On-<br>going | All           | On-<br>going  | All           | On-<br>going | All           | On-<br>going | All           | On-<br>going | All            | On-<br>going | All |
| Rheuma       | oid arthriti  | s             |               |              |               |              |               |              |                |              |     |
| 5            | 10            | 6             | 27            | 1            | 4             | 0            | 1             | 7            | 16             | 19           | 58  |
| Crohns o     | isease        |               |               |              |               |              |               |              |                |              |     |
| 1            | 4             | 0             | 16            | 1            | 8             | 0            | 1             | 3            | 7              | 5            | 36  |
| Psoriasis    |               |               |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 1             | 1             | 0            | 2             | 0            | 1             | 0            | 0              | 1            | 4   |
| Ankylosii    | ng spondyl    | itis          |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 2             | 2             | 0            | 0             | 0            | 0             | 0            | 0              | 2            | 2   |
| Juvenile     | rheumatoi     | d arthritis   |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 1             | 1             | 0            | 0             | 0            | 0             | 0            | 1              | 1            | 2   |
| Ulcerativ    | e colitis     |               |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0             | 0             | 0            | 1             | 0            | 0             | 0            | 1              | 0            | 2   |
| Metastat     | c non sma     | all cell lung | cancer        |              |               |              |               |              |                |              |     |
| 0            | 0             | 0             | 0             | 0            | 0             | 1            | 1             | 0            | 0              | 1            | 1   |
| Encepha      | litis         |               |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0             | 0             | 0            | 0             | 0            | 0             | 1            | 1              | 1            | 1   |
| Inflamma     | tory bowe     | l disease     |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0             | 0             | 0            | 0             | 0            | 0             | 1            | 1              | 1            | 1   |
| Psoriatic    | arthritis     |               |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 1             | 1             | 0            | 0             | 0            | 0             | 0            | 0              | 1            | 1   |
| Spontane     | eous abort    | ion           |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0             | 0             | 0            | 0             | 0            | 0             | 0            | 1              | 0            | 1   |
| Vascular     | disease       |               |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0             | 0             | 0            | 0             | 0            | 0             | 0            | 1              | 0            | 1   |



| Interstitial lung disease |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|
| 0                         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Cardiac failure           |   |   |   |   |   |   |   |   |   |   |   |
| 0                         | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Synovitis                 |   |   |   |   |   |   |   |   |   |   |   |
| 0                         | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Edema                     |   |   |   |   |   |   |   |   |   |   |   |
| 0                         | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |

## Total Trials by Phase and Status

|                           | se 4<br>nical |              | ise 3<br>nical |              | se 2<br>nical |              | se 1<br>nical |              | ase<br>ecified | То           | tal |
|---------------------------|---------------|--------------|----------------|--------------|---------------|--------------|---------------|--------------|----------------|--------------|-----|
| On-<br>going              | All           | On-<br>going | All            | On-<br>going | All           | On-<br>going | All           | On-<br>going | All            | On-<br>going | All |
| Total by Phase and Status |               |              |                |              |               |              |               |              |                |              |     |
| 6                         | 14            | 10           | 48             | 2            | 15            | 3            | 6             | 10           | 27             | 31           | 110 |

#### **Phase Definitions**

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

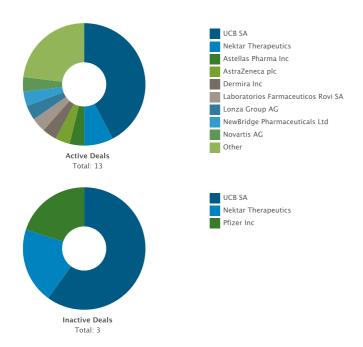
## Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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# certolizumab pegol DEALS AND PATENTS

# DEALS Deals by Parent Company Chart

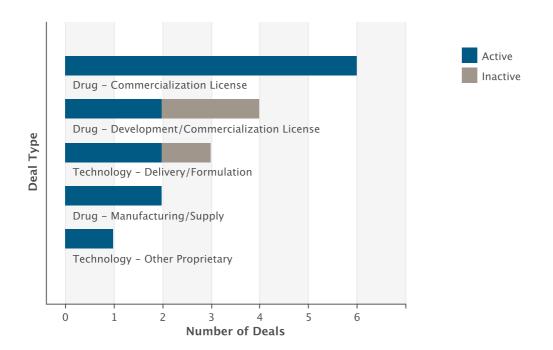


# **Deals by Parent Company Table**

| Company Name                       | <b>Prin</b><br>Active | ncipal<br>Inactive |   | tner<br>Inactive | Total |
|------------------------------------|-----------------------|--------------------|---|------------------|-------|
| UCB SA                             | 7                     | 2                  | 4 | 2                | 14    |
| Nektar Therapeutics                | 2                     | 1                  | 0 | 0                | 3     |
| Pfizer Inc                         | 0                     | 0                  | 1 | 1                | 2     |
| Dermira Inc                        | 0                     | 0                  | 1 | 0                | 1     |
| Orient Europharma                  | 0                     | 0                  | 1 | 0                | 1     |
| Astellas Pharma Inc                | 0                     | 0                  | 1 | 0                | 1     |
| XOMA Corp                          | 1                     | 0                  | 0 | 0                | 1     |
| Novartis AG                        | 1                     | 0                  | 0 | 0                | 1     |
| NewBridge Pharmaceuticals Ltd      | 0                     | 0                  | 1 | 0                | 1     |
| Lonza Group AG                     | 1                     | 0                  | 0 | 0                | 1     |
| Laboratorios Farmaceuticos Rovi SA | 0                     | 0                  | 1 | 0                | 1     |
| Royalty Pharma                     | 0                     | 0                  | 1 | 0                | 1     |
| Otsuka Holdings Co Ltd             | 0                     | 0                  | 1 | 0                | 1     |
| OXO                                | 1                     | 0                  | 0 | 0                | 1     |
| AstraZeneca plc                    | 0                     | 0                  | 1 | 0                | 1     |



## **Deals by Type Chart**



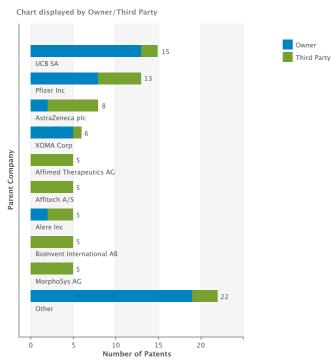
# **Deals by Type Table**

| Deal Type                                    | Active | Inactive | Total |
|--|--------|----------|-------|
| Drug - Commercialization License             | 6      | 0        | 6     |
| Drug - Development/Commercialization License | 2      | 2        | 4     |
| Technology - Delivery/Formulation            | 2      | 1        | 3     |
| Drug - Manufacturing/Supply                  | 2      | 0        | 2     |
| Technology - Other Proprietary               | 1      | 0        | 1     |



## **PATENTS**

## **Patents by Parent Company Chart**



# **Patents by Parent Company Table**

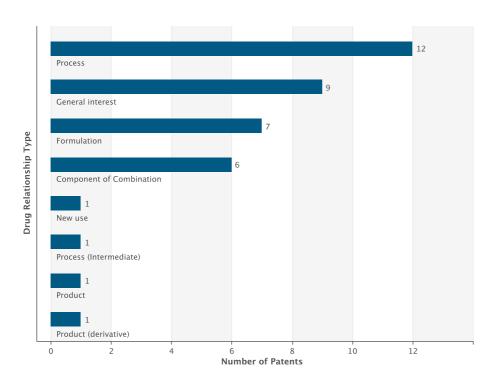
| Company Name                      | As Owner | As Third Party | Total |
|-----------------------------------|----------|----------------|-------|
| UCB SA                            | 13       | 2              | 15    |
| Pfizer Inc                        | 8        | 5              | 13    |
| AstraZeneca plc                   | 2        | 6              | 8     |
| XOMA Corp                         | 5        | 1              | 6     |
| Nestle SA                         | 5        | 0              | 5     |
| MorphoSys AG                      | 0        | 5              | 5     |
| BioInvent International AB        | 0        | 5              | 5     |
| Affitech A/S                      | 0        | 5              | 5     |
| Affimed Therapeutics AG           | 0        | 5              | 5     |
| Alere Inc                         | 2        | 3              | 5     |
| Verenium Corp                     | 0        | 5              | 5     |
| Dyax Corp                         | 0        | 4              | 4     |
| Takeda Pharmaceutical Co Ltd      | 3        | 1              | 4     |
| Novartis AG                       | 1        | 2              | 3     |
| Roche Holding AG                  | 2        | 2              | 3     |
| Alexion Pharmaceuticals Inc       | 1        | 2              | 2     |
| Eli Lilly & Co                    | 0        | 2              | 2     |
| Boehringer Ingelheim Corp         | 1        | 1              | 2     |
| Medical Research Council (MRC)    | 0        | 2              | 2     |
| Biogen Idec Inc                   | 1        | 1              | 2     |
| Merck & Co Inc                    | 0        | 2              | 2     |
| Bristol-Myers Squibb Co           | 0        | 2              | 2     |
| Oregon Health Sciences University | 1        | 0              | 1     |
| Imperial College London           | 1        | 0              | 1     |
| Seattle Genetics Inc              | 1        | 0              | 1     |
| GlaxoSmithKline plc               | 0        | 1              | 1     |
|                                   |          |                |       |



| The University Health Network       | 1 | 0 | 1 |
|-------------------------------------|---|---|---|
| Institute for Neurological Research | 0 | 1 | 1 |
| BioTransplant Inc                   | 0 | 1 | 1 |
| Bayer AG                            | 0 | 1 | 1 |
| Sanofi                              | 0 | 1 | 1 |
| Astellas Pharma Inc                 | 1 | 0 | 1 |
| TACT IP LLC                         | 1 | 0 | 1 |
| FUJIFILM Holdings Corp              | 0 | 1 | 1 |
| Otsuka Holdings Co Ltd              | 1 | 0 | 1 |
| Life Technologies Corp              | 0 | 1 | 1 |
| OXO                                 | 0 | 1 | 1 |
| Universite de Nantes                | 0 | 1 | 1 |
| Royalty Pharma                      | 1 | 0 | 1 |
| Mochida Pharmaceutical Co Ltd       | 1 | 0 | 1 |
| Merck KGaA                          | 0 | 1 | 1 |
| University of Oxford                | 1 | 0 | 1 |
| Laboratorios Farmaceuticos Rovi SA  | 1 | 0 | 1 |
| E I DuPont de Nemours & Co          | 0 | 1 | 1 |
| Unilever                            | 0 | 1 | 1 |
| INSERM                              | 1 | 0 | 1 |
| Biotest AG                          | 0 | 1 | 1 |
| PDL BioPharma Inc                   | 1 | 1 | 1 |
| Johnson & Johnson                   | 0 | 1 | 1 |
| Johnson Matthey plc                 | 1 | 0 | 1 |
| Dompe Group                         | 0 | 1 | 1 |
|                                     |   |   |   |



# **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

| Drug Relationship        | Total |
|--------------------------|-------|
| Process                  | 12    |
| General interest         | 9     |
| Formulation              | 7     |
| Component of Combination | 6     |
| Process (Intermediate)   | 1     |
| Product                  | 1     |
| New use                  | 1     |
| Product (derivative)     | 1     |



## **DRM-02**

#### **DRM-02 SNAPSHOT**

| Drug Name            | DRM-02  |
|----------------------|---|
| Key Synonyms         |   |
| Originator Company   | Valocor Therapeutics Ltd                              |
| Active Companies     | Dermira Inc   |
| Inactive Companies   | Valocor Therapeutics Ltd                              |
| Highest Status       | Phase 2 Clinical                                      |
| Active Indications   | Rosacea;Atopic dermatitis;Psoriasis                   |
| Target-based Actions | PDE 4 inhibitor;Integrin-linked kinase inhibitor      |
| Other Actions        | Dermatological agent                                  |
| Technologies         | Dermatological formulation;Small molecule therapeutic |
| Last Change Date     | 03-Jul-2014   |

## **DRM-02 DEVELOPMENT PROFILE**

## **SUMMARY**

Dermira, following its acquisition of Valocor, is developing DRM-02 (formerly VAL-002, QLT-418, QLT-0418), a Th-2 type small-molecule kinase and PDE4 inhibitor and a lead from series of integrin-linked kinase (ILK) inhibitors, for the potential topical treatment of chronic inflammatory skin diseases including atopic dermatitis, rosacea and plaque psoriasis, .. In October 2013, three phase II trials were initiated to assess the effectiveness of DRM-02 in the treatment of atopic dermatitis, rosacea and plaque psoriasis, respectively, ; in February 2014, enrollment was completed in all the three phase IIa trials. At that time, data were expected in the second quarter of 2014.

This program was previously described as VAL-003. However, the company used the research code VAL-003 to describe a drug for vitiligo.

## **DRM-02 DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

| Company     | Indication        | Country | <b>Development Status</b> | Date        |
|-------------|-------------------|---------|---------------------------|-------------|
| Dermira Inc | Atopic dermatitis | Canada  | Phase 2 Clinical          | 31-Oct-2013 |
| Dermira Inc | Psoriasis         | Canada  | Phase 2 Clinical          | 31-Oct-2013 |
| Dermira Inc | Rosacea           | Canada  | Phase 2 Clinical          | 31-Oct-2013 |



## **DRM-02 DRUG NAMES**

| Names  | Туре          |
|--|---------------|
| integrin-linked kinase inhibitors (skin disorders),<br>Dermira |               |
| integrin-linked kinase inhibitors (skin disorders),<br>Valocor |               |
| VAL-002  | Research Code |
| ILK inhibitors (skin disorders), Dermira                       |               |
| DRM-02   | Research Code |
| QLT-418  | Research Code |
| QLT-0418   | Research Code |
| ILK inhibitors (skin disorders), Valocor                       |               |

# **DRM-02 CLINICAL TRIALS**

# Trials by Phase and Condition Studied

|              | se 4<br>nical |              | se 3<br>nical | Pha<br>Clin  | se 2<br>lical | Pha<br>Clir  | se 1<br>nical |              | ase<br>ecified | То           | tal |
|--------------|---------------|--------------|---------------|--------------|---------------|--------------|---------------|--------------|----------------|--------------|-----|
| On-<br>going | All            | On-<br>going | All |
| Psoriasis    | <b>;</b>      |              |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 0             | 0            | 1             | 0            | 0             | 0            | 0              | 0            | 1   |
| Rosacea      |               |              |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 0             | 0            | 1             | 0            | 0             | 0            | 0              | 0            | 1   |
| Atopic de    | ermatitis     |              |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 0             | 0            | 1             | 0            | 0             | 0            | 0              | 0            | 1   |

## Total Trials by Phase and Status

|                           | Phase 4 Phase 3 Clinical |              | Phase 2<br>Clinical |              | Phase 1<br>Clinical |              | Phase<br>Unspecified |              | Total |              |     |
|---------------------------|--------------------------|--------------|---------------------|--------------|---------------------|--------------|----------------------|--------------|-------|--------------|-----|
| On-<br>going              | All                      | On-<br>going | All                 | On-<br>going | All                 | On-<br>going | All                  | On-<br>going | All   | On-<br>going | All |
| Total by Phase and Status |                          |              |                     |              |                     |              |                      |              |       |              |     |
| 0                         | 0                        | 0            | 0                   | 0            | 3                   | 0            | 0                    | 0            | 0     | 0            | 3   |

**Phase Definitions** 



#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

# **lemuteporfin**

## **lemuteporfin SNAPSHOT**

| Drug Name            | lemuteporfin  |
|----------------------|---|
| Key Synonyms         | lemuteporfin  |
| Originator Company   | QLT Inc   |
| Active Companies     | Dermira Inc   |
| Inactive Companies   | Valocor Therapeutics Ltd;QLT Inc  |
| Highest Status       | Phase 2 Clinical  |
| Active Indications   | Acne  |
| Target-based Actions |   |
| Other Actions        | Anticancer;Photosensitizer;Systemic antipsoriatic product;Immunomodulator     |
| Technologies         | Dermatological formulation;Small molecule therapeutic;Intravenous formulation |
| Last Change Date     | 21-Jun-2013   |

## **lemuteporfin DEVELOPMENT PROFILE**

## **SUMMARY**

Dermira, following its acquisition of Valocor Therapeutics (which had been spun-out from QLT), is developing lemuteporfin (QLT-0074, DRM-05), a benzoporphyrin-derived chlorin-like photosensitizer, as a potential topical photodynamic therapy for acne,. In December 2011, a phase I/II trial began.

Previously, QLT had been developing the compound and by January 2008, proof-of-concept clinical studies for moderate to severe acne had begun. However, in July 2008, the company announced it had re-evaluated the continuation of development of the drug based on interim results of a phase I/II study of an iv formulation, and was halting development of the drug for the treatment of acne. QLT was previously developing lemuteporfin for the potential treatment of androgenic alopecia, benign prostate hyperplasia (BPH), various immune disorders and cancer . However, no development has been reported for the immune disorders since mid-2000 and for cancer since 2005 ; development for androgenic alopecia was halted during 2004. By September 2005, a phase IIb trial in BPH was underway; however in February 2006, the trial had failed to meet its primary efficacy objective at 3 months. At that time, the company said that the data did not support phase III trials, and it planned to complete data analysis of the trial in order to determine the best path forward; no further development was reported for this indication.

## **lemuteporfin DEVELOPMENT STATUS**

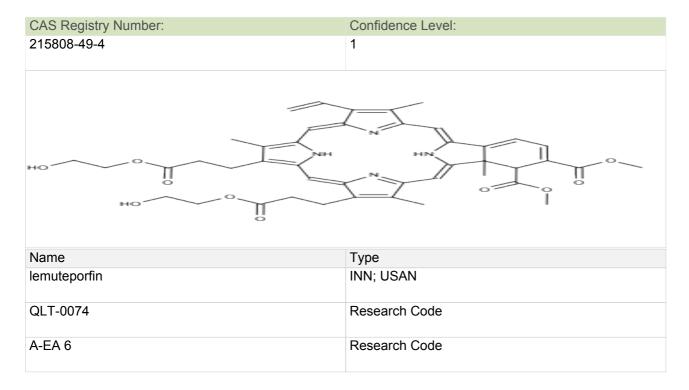
## **CURRENT DEVELOPMENT STATUS**

| CORRENT DEVELOP | VIENT STATUS |         |                           |             |
|-----------------|--------------|---------|---------------------------|-------------|
| Company         | Indication   | Country | <b>Development Status</b> | Date        |
| Dermira Inc     | Acne         | Canada  | Phase 2 Clinical          | 12-Dec-2011 |
| QLT Inc         | Acne         | Canada  | Discontinued              | 26-Jul-2008 |



| Company | Indication           | Country   | Development Status      | Date        |
|---------|----------------------|-----------|-------------------------|-------------|
| QLT Inc | Alopecia             | Canada    | Discontinued            | 31-Dec-2004 |
| QLT Inc | Cancer               | Canada    | No Development Reported | 17-Jan-2008 |
| QLT Inc | Prostate hyperplasia | Argentina | No Development Reported | 17-Jan-2008 |
| QLT Inc | Prostate hyperplasia | Canada    | No Development Reported | 17-Jan-2008 |
| QLT Inc | Prostate hyperplasia | US        | No Development Reported | 17-Jan-2008 |
| QLT Inc | Psoriasis            | Canada    | No Development Reported | 01-Jan-2002 |
| QLT Inc | Psoriatic arthritis  | Canada    | No Development Reported | 01-Jan-2002 |
| QLT Inc | Rheumatoid arthritis | Canada    | No Development Reported | 01-Jan-2002 |

# **lemuteporfin CHEMICAL STRUCTURES**





## **lemuteporfin DRUG NAMES**

| Names  | Туре          |
|--|---------------|
| DRM-05   | Research Code |
| QLT-00748                                      | Research Code |
| third generation photosensitizers, QLT/Valocor |               |
| A-EA 6   | Research Code |
| immunomodulator, QLT/Valocor                   |               |
| lemuteporfin                                   | INN, USAN     |
| QLT-0074                                       | Research Code |

# **lemuteporfin CLINICAL TRIALS**

# Trials by Phase and Condition Studied

|              | se 4<br>nical |              | se 3<br>nical | Pha<br>Clin  | se 2<br>lical |              | se 1<br>iical | Pha<br>Unspe | ase<br>ecified | То           | tal |
|--------------|---------------|--------------|---------------|--------------|---------------|--------------|---------------|--------------|----------------|--------------|-----|
| On-<br>going | All            | On-<br>going | All |
| Prostate     | hyperplasi    | ia           |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 0             | 0            | 1             | 0            | 2             | 0            | 0              | 0            | 3   |
| Alopecia     |               |              |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 0             | 0            | 1             | 0            | 0             | 0            | 0              | 0            | 1   |
| Acne         |               |              |               |              |               |              |               |              |                |              |     |
| 0            | 0             | 0            | 0             | 0            | 1             | 0            | 0             | 0            | 0              | 0            | 1   |

# Total Trials by Phase and Status

|                           | ase 4 Phase 3<br>nical Clinical |              | Phase 2<br>Clinical |              | Phase 1<br>Clinical |              | Phase<br>Unspecified |              | Total |              |     |
|---------------------------|---------------------------------|--------------|---------------------|--------------|---------------------|--------------|----------------------|--------------|-------|--------------|-----|
| On-<br>going              | All                             | On-<br>going | All                 | On-<br>going | All                 | On-<br>going | All                  | On-<br>going | All   | On-<br>going | All |
| Total by Phase and Status |                                 |              |                     |              |                     |              |                      |              |       |              |     |
| 0                         | 0                               | 0            | 0                   | 0            | 3                   | 0            | 3                    | 0            | 0     | 0            | 6   |

#### **Phase Definitions**

Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)



#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

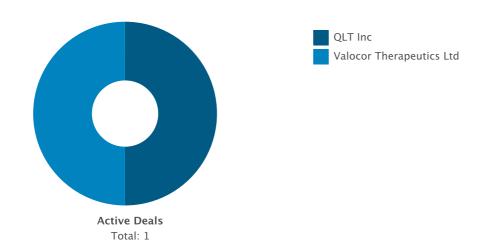
# Phase 1 Clinical

Includes Phase 1, Phase 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

## **lemuteporfin DEALS AND PATENTS**

DEALS

Deals by Parent Company Chart



## **Deals by Parent Company Table**

| Company Name             |   | <b>cipal</b><br>Inactive | Par<br>Active | Total |   |
|--------------------------|---|--------------------------|---------------|-------|---|
| Valocor Therapeutics Ltd | 0 | 0                        | 1             | 0     | 1 |
| QLT Inc                  | 1 | 0                        | 0             | 0     | 1 |

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# **Deals by Type Chart**



# **Deals by Type Table**

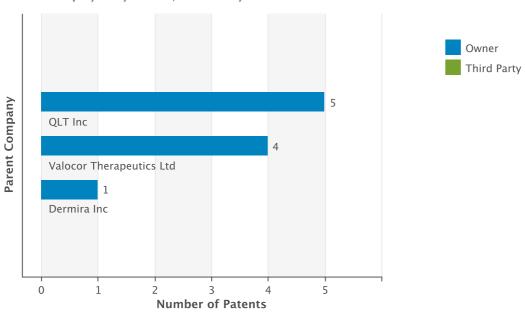
| Deal Type                                    | Active | Inactive | Total |
|--|--------|----------|-------|
| Drug - Development/Commercialization License | 1      | 0        | 1     |

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## **PATENTS**

# **Patents by Parent Company Chart**

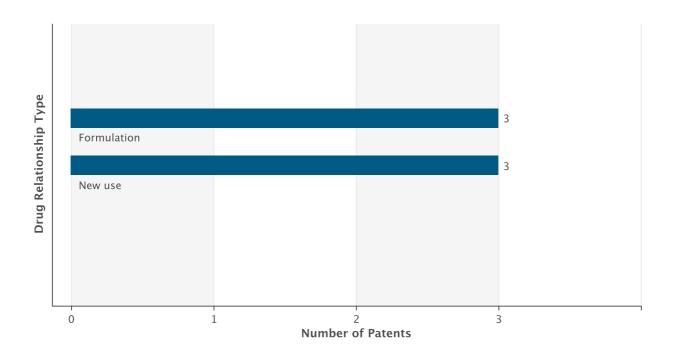
Chart displayed by Owner/Third Party



# **Patents by Parent Company Table**

| Company Name             | As Owner | As Third Party | Total |
|--------------------------|----------|----------------|-------|
| QLT Inc                  | 5        | 0              | 5     |
| Valocor Therapeutics Ltd | 4        | 0              | 4     |
| Dermira Inc              | 1        | 0              | 1     |

# **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

| Drug Relationship | Total |
|-------------------|-------|
| Formulation       | 3     |
| New use           | 3     |

## DRM-04B

#### **DRM-04B SNAPSHOT**

| Drug Name            | DRM-04B   |
|----------------------|---|
| Key Synonyms         |   |
| Originator Company   | Dermira Inc   |
| Active Companies     | Dermira Inc   |
| Inactive Companies   |   |
| Highest Status       | Phase 2 Clinical                                      |
| Active Indications   | Hyperhidrosis   |
| Target-based Actions | Acetylcholine receptor antagonist                     |
| Other Actions        |   |
| Technologies         | Dermatological formulation;Small molecule therapeutic |
| Last Change Date     | 13-Nov-2014   |

## **DRM-04B DEVELOPMENT PROFILE**

## **SUMMARY**

Dermira is developing DRM-04B (DRM-04), an anticholinergic, for the potential topical treatment of axillary hyperhidrosis. In November 2013, a phase II trial was initiated. In February 2014, patient enrollment was ongoing; in November 2014, results were reported. In April 2014, another phase II trial was initiated; in November 2014, data were expected in the first half of 2015. At that time, the company planned to initiate a phase III trial in the second half of 2015.

## **DRM-04B DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

| Company     | Indication    | Country | <b>Development Status</b> | Date        |
|-------------|---------------|---------|---------------------------|-------------|
| Dermira Inc | Hyperhidrosis | US      | Phase 2 Clinical          | 30-Nov-2013 |
|             |               |         |                           |             |

#### **DRM-04B DRUG NAMES**

| Names   | Туре          |
|---------|---------------|
| DRM-04B | Research Code |
| DRM-04  | Research Code |

## **DRM-04B CLINICAL TRIALS**



## Trials by Phase and Condition Studied

|               | hase 4 Phase 3<br>Ilinical Clinical |              | Phase 2<br>Clinical |              | Phase 1<br>Clinical |              | Phase<br>Unspecified |              | Total |              |     |
|---------------|-------------------------------------|--------------|---------------------|--------------|---------------------|--------------|----------------------|--------------|-------|--------------|-----|
| On-<br>going  | All                                 | On-<br>going | All                 | On-<br>going | All                 | On-<br>going | All                  | On-<br>going | All   | On-<br>going | All |
| Hyperhidrosis |                                     |              |                     |              |                     |              |                      |              |       |              |     |
| 0             | 0                                   | 0            | 0                   | 0            | 2                   | 0            | 0                    | 0            | 0     | 0            | 2   |

## Total Trials by Phase and Status

|                           | Phase 4 Phase 3<br>Clinical Clinical |              | Phase 2<br>Clinical |              | Phase 1<br>Clinical |              | Phase<br>Unspecified |              | Total |              |     |
|---------------------------|--------------------------------------|--------------|---------------------|--------------|---------------------|--------------|----------------------|--------------|-------|--------------|-----|
| On-<br>going              | All                                  | On-<br>going | All                 | On-<br>going | All                 | On-<br>going | All                  | On-<br>going | All   | On-<br>going | All |
| Total by Phase and Status |                                      |              |                     |              |                     |              |                      |              |       |              |     |
| 0                         | 0                                    | 0            | 0                   | 0            | 2                   | 0            | 0                    | 0            | 0     | 0            | 2   |

## **Phase Definitions**

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

## Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0  $\,$ 

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## **DRM-01**

#### **DRM-01 SNAPSHOT**

| Drug Name            | DRM-01  |
|----------------------|---|
| Key Synonyms         |   |
| Originator Company   | Valocor Therapeutics Ltd                                      |
| Active Companies     | Dermira Inc   |
| Inactive Companies   | Valocor Therapeutics Ltd                                      |
| Highest Status       | Phase 2 Clinical  |
| Active Indications   | Acne;Sebaceous gland disease;Acne vulgaris                    |
| Target-based Actions |   |
| Other Actions        | Unspecified drug target;Anti-inflammatory                     |
| Technologies         | Dermatological formulation;Prodrug;Small molecule therapeutic |
| Last Change Date     | 13-Nov-2014   |

## **DRM-01 DEVELOPMENT PROFILE**

## **SUMMARY**

Dermira, following its acquisition of Valocor Therapeutics, is developing DRM-01 (previously VAL-001; DRM-01B), a topical sebum inhibitor, for the potential treatment of acne including acne vulgaris and sebaceous gland hyperactivity. In August 2013, a phase I/II study was initiated in healthy volunteers with acne vulgaris; in November 2014, results were reported. At that time, the company planned to file an IND with the FDA to initiate a phase IIb trial in the first half of 2015.

## **DRM-01 DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

| CONNENT DEVELOP | VILITI STATUS           |         |                           |             |
|-----------------|-------------------------|---------|---------------------------|-------------|
| Company         | Indication              | Country | <b>Development Status</b> | Date        |
| Dermira Inc     | Acne vulgaris           | Canada  | Phase 2 Clinical          | 31-Aug-2013 |
| Dermira Inc     | Acne                    | US      | Discovery                 | 20-Oct-2011 |
| Dermira Inc     | Sebaceous gland disease | US      | Discovery                 | 20-Oct-2011 |



#### **DRM-01 DRUG NAMES**

| Names   | Туре          |
|---|---------------|
| sebum inhibitor (topical, acne), Valocor Therapeutics |               |
| VAL-001, Valocor                                      | Research Code |
| DRM-01B   | Research Code |
| DRM-01  | Research Code |
| sebum inhibitor (topical, acne), Dermira              |               |

## **DRM-01 CLINICAL TRIALS**

## Trials by Phase and Condition Studied

| Phase 4 Phase 3<br>Clinical Clinical |     | Phase 2<br>Clinical |     | Phase 1<br>Clinical |     | Phase<br>Unspecified |     | Total        |     |              |     |
|--------------------------------------|-----|---------------------|-----|---------------------|-----|----------------------|-----|--------------|-----|--------------|-----|
| On-<br>going                         | All | On-<br>going        | All | On-<br>going        | All | On-<br>going         | All | On-<br>going | All | On-<br>going | All |
| Acne vulgaris                        |     |                     |     |                     |     |                      |     |              |     |              |     |
| 0                                    | 0   | 0                   | 0   | 0                   | 1   | 0                    | 0   | 0            | 0   | 0            | 1   |

## Total Trials by Phase and Status

|                           | Phase 4 Phase 3<br>Clinical Clinical |              | Phase 2<br>Clinical |              | Phase 1<br>Clinical |              | Phase<br>Unspecified |              | Total |              |     |
|---------------------------|--------------------------------------|--------------|---------------------|--------------|---------------------|--------------|----------------------|--------------|-------|--------------|-----|
| On-<br>going              | All                                  | On-<br>going | All                 | On-<br>going | All                 | On-<br>going | All                  | On-<br>going | All   | On-<br>going | All |
| Total by Phase and Status |                                      |              |                     |              |                     |              |                      |              |       |              |     |
| 0                         | 0                                    | 0            | 0                   | 0            | 1                   | 0            | 0                    | 0            | 0     | 0            | 1   |

## **Phase Definitions**

## Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

## Phase 1 Clinical

Includes Phase 1, Phase 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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