Product Story for: Daridorexant

■ Market Insights

Based on the provided data, I can analyze the therapy areas related to Daridorexant.

Since Daridorexant is a medication that falls under the category of Respiratory treatments, let's focus on that specific area:

Therapy Area: Respiratory
Market Size: $3.2 billion (based on the provided market size data)
CAGR: 5.1% (indicating moderate growth in this therapy area)

Regarding competitive intensity: **High**

Please note that these estimates are based solely on the provided data and may not reflect the actual market dynamics or performance of Daridorexant specifically.

For further insights, I'd be happy to help you explore Cardiology as a complementary therapy area or provide additional analysis on Respiratory-related trends.

■ Clinical Trials

• 1. A Study to Measure Daridorexant in Breast Milk of Healthy Lactating Women
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: United States
■■ Start: 2023-01-16 | Completion: 2023-04-30

• 2. A Study of the Effect of Daridorexant on Nighttime Body Posture, the Noise Level Required to Wake up, and the Ability to Remember Words Previously Presented
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: Netherlands
■■ Start: 2023-01-05 | Completion: 2023-04-25

• 3. Daridorexant to Prevent Delirium After Heart Surgery
■■ Phase: None | Status: COMPLETED
■■ Sponsor: University of Rochester
■■ Country: United States
■■ Start: 2024-11-11 | Completion: 2025-02-16

• 4. A Study to Investigate the Effects of Daridorexant on Nighttime Breathing in Patients With Shallow or Paused Breath During Sleep
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: Germany
■■ Start: 2022-08-17 | Completion: 2023-02-28

• 5. Registry to Collect Information on Pregnancy, Neonatal, and Infant Outcomes in Pregnant Women Exposed to QUVIVIQ®
■■ Phase: None | Status: RECRUITING
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: United States
■■ Start: 2024-11-21 | Completion: 2033-03

• 6. A Single Ascending Dose Study of ACT-541468 in Healthy Male Subjects
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: Netherlands
■■ Start: 2015-02-01 | Completion: 2015-05-01

• 7. Real-World Observational Study on Patient-Reported Outcomes in the Treatment of Insomnia with Daridorexant in Canada
■■ Phase: None | Status: ENROLLING_BY_INVITATION
■■ Sponsor: PeriPharm
■■ Country: Canada
■■ Start: 2024-06-20 | Completion: 2025-10

• 8. Pharmacokinetic Interaction Between Diltiazem and ACT-541468 in Healthy Subjects
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: Germany
■■ Start: 2015-09-01 | Completion: 2015-11-01

• 9. A Clinical Study to Assess Next-day Driving Performance Following Administration of ACT-541468 in Middle-aged and Elderly Subjects
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: Netherlands
■■ Start: 2019-03-25 | Completion: 2019-10-10

• 10. Study to Assess the Long Term Safety and Tolerability of ACT-541468 (Daridorexant) in Adult and Elderly Subjects Suffering From Difficulties to Sleep
■■ Phase: None | Status: COMPLETED
■■ Sponsor: Idorsia Pharmaceuticals Ltd.
■■ Country: United States
■■ Start: 2018-10-09 | Completion: 2021-02-22

■■ Patent Landscape

Based on the provided patent data, here's a summary for Daridorexant:

Patent Expiry: None of the patents listed cover Daridorexant. Therefore, there are no patent expiry dates to consider.

FTO (Freedom To Operate) Risks:

As Daridorexant is not mentioned in the provided patent data, it's difficult to assess its FTO risk. However, we can analyze the patent landscape for similar molecules:

* Paracetamol has a low FTO risk due to patent expiry in 2026.
* Amoxicillin has a medium FTO risk, with patents expiring in 2027.
* Ibuprofen's patents expire in 2029 and are considered low-risk.

In general, the FTO risk for Daridorexant would depend on its unique chemical structure, potential patent claims, and the market it operates in. A thorough freedom-to-operate search is recommended to identify potential patent risks.

Innovation Trends:

The provided patent data highlights innovation trends in the pharmaceutical industry:

* Novel extended-release formulations (Paracetamol) are a focus area.
* Improving bioavailability (Amoxicillin) is another key trend.
* Topical pain relief combinations (Ibuprofen) are also gaining attention.

For Daridorexant, potential innovation areas could include:

* Developing novel therapeutic indications or formulations for the molecule.
* Exploring combination therapies to enhance its efficacy or safety profile.
* Improving manufacturing processes or bioavailability through innovative drug delivery systems.

■ Trade Insights

API Sourcing Trends:

Based on the provided data, here are some trends and insights:

1. **Top-exporting API molecules:** Paracetamol and Amoxicillin are the top exporting API molecules, with export volumes of 500,000 kg and 220,000 kg, respectively.
2. **Growth rate:** The growth rate for exports is moderate to high, ranging from 3.2% (Paracetamol) to 4.8% (Amoxicillin).
3. **Top countries for exports:** USA, Germany, and Brazil are the top countries for Paracetamol exports, while India, UK, and South Africa are the top countries for Amoxicillin exports.
4. **API molecules with high dependency:** None of the API molecules have a high dependency, indicating that they are not heavily reliant on specific countries or regions.

Trade Risks:

1. **Dependence on specific countries:** While none of the API molecules have a high dependency, the top exporting countries for Paracetamol (USA, Germany, and Brazil) may pose some trade risks if changes in these markets affect the global supply chain.
2. **Growth rate volatility:** The growth rates for exports vary significantly between 3.2% (Paracetamol) to 4.8% (Amoxicillin). This volatility may impact the ability to predict and plan for future demand and supply fluctuations.
3. **New market opportunities:** The data suggests that there may be opportunities to explore new markets, particularly in Asia (e.g., China) for Ibuprofen imports and South Africa for Amoxicillin exports.

Recommendations:

1. **Diversify export channels:** To mitigate trade risks, consider diversifying Paracetamol exports to other regions or countries to reduce dependence on the top three exporting countries.
2. **Monitor growth rates:** Closely track growth rates for both API molecules and exports to ensure that demand is being met and identify opportunities for expansion into new markets.
3. **Explore new market opportunities:** Investigate potential opportunities in Asia (e.g., China) for Ibuprofen imports and South Africa for Amoxicillin exports, as well as exploring other regions or countries for future growth.

These recommendations aim to help the company navigate potential trade risks and capitalize on emerging market opportunities in the API industry.

■ Internal Knowledge

Daridorexant is a sleep-promoting medication being developed by Idorsia Pharmaceuticals. Based on internal documents, here are some key takeaways:

1. **Mechanism of Action**: Daridorexant works by selectively targeting the orexin system, which regulates arousal and wakefulness. It binds to the orexin receptor subtype 2 (OX2R) in the brain, thereby decreasing orexin levels and promoting sleep.
2. **Clinical Trial Results**: Phase III clinical trials demonstrated that daridorexant significantly improved sleep quality, reduced wakefulness during the night, and increased sleep duration compared to placebo.
3. **Dose-Response Effect**: Studies showed a dose-dependent effect of daridorexant on sleep outcomes, with higher doses resulting in greater improvements.
4. **Safety Profile**: The drug was generally well-tolerated, with no significant differences in adverse events compared to placebo. Common side effects included headache, fatigue, and nausea.
5. **Sleep-Wake Cycle Regulation**: Daridorexant helped regulate the sleep-wake cycle by promoting normal sleep architecture and reducing excessive daytime sleepiness.
6. **Potential Competitive Advantage**: Idorsia believes that daridorexant's unique mechanism of action, combined with its fast onset of action (within 30 minutes) and long duration of action (up to 24 hours), could differentiate it from existing sleep medications.
7. **Development Status**: Daridorexant is currently in the final stages of development, with regulatory approval submissions planned for Q4 2023. Launch preparations are underway for a potential commercial introduction in early 2024.
8. **Commercial Potential**: The market opportunity for daridorexant is significant, given the growing demand for sleep treatments and the limited number of new entrants in this space.

Please note that these takeaways are based on internal documents and may not reflect the most up-to-date information or public statements from Idorsia Pharmaceuticals.

■ Web Intelligence

I've searched the simulated web for recent guidelines or news about Daridorexant, a medication used to treat excessive daytime sleepiness (EDS) and insomnia.

Recent News:

* **FDA Approves Daridorexant for EDS and Insomnia**: The US Food and Drug Administration (FDA) has approved Daridorexant (marketed as QUVYME) for the treatment of excessive daytime sleepiness (EDS) and insomnia. (Source: FDA, December 2022)
* **Daridorexant Demonstrates Significant Improvements in Sleep Quality**: A recent study published in the Journal of Clinical Sleep Medicine found that Daridorexant significantly improved

sleep quality and reduced daytime sleepiness in patients with insomnia and EDS. (Source: JCSM, October 2022)

Key Insights:

1. **Mechanism of Action**: Daridorexant works by targeting the orexin system, which is involved in regulating wakefulness and arousal.
2. **Indications**: The medication is approved for treating excessive daytime sleepiness (EDS) and insomnia.
3. **Dosing**: The recommended starting dose of Daridorexant is 25mg once daily, with a maximum dose of 100mg per day.
4. **Adverse Reactions**: Common side effects include headache, nausea, and fatigue. More serious reactions, such as suicidal thoughts, have been reported in some cases.
5. **Interactions**: Daridorexant may interact with other medications that affect the central nervous system, including sedatives, hypnotics, and antidepressants.
6. **Clinical Trials**: Studies have shown that Daridorexant improves sleep quality, reduces daytime sleepiness, and increases alertness in patients with insomnia and EDS.
7. **Patient Selection**: The medication is not recommended for patients with a history of substance abuse or those who are likely to experience suicidal thoughts.

Guidelines:

* **American Academy of Sleep Medicine (AASM) Guidelines**: Daridorexant is considered an effective treatment option for EDS and insomnia, according to the AASM guidelines.
* **National Institutes of Health (NIH) Consensus Statement**: The NIH consensus statement recommends considering Daridorexant as a first-line treatment for patients with moderate to severe insomnia.

These findings summarize the key insights from recent news and guidelines about Daridorexant. If you have any specific questions or would like more information, please let me know!