|  |  |  |  |
| --- | --- | --- | --- |
| **Project Name (internal)** | SS Biosimilars | **Project Code** | PB4LSS023 |
| **Project Manager** | Saskia Speth | **Clinical Program Manager** | Chelsey Goins |
| **Compliance** | ---------- | **Editor** | Heather Tomlinson |

Please add your content to the form below and remove any content that is irrelevant to your activity. If something gets updated, please update this document.

**\*\*\*DO NOT LIST “SEE ATTACHED DOCUMENT”.**

**This is the only copy document that should be sent to Design.\*\*\***

**Items highlighted in YELLOW should be completed by the Clinical Team**

**Items highlighted in TEAL should be determined at the Kickoff Meeting**

**Items highlighted in GREEN are the Minimum Required Sections for creating an invite.**

1. **[Title---always italicized, no bold, no quotes]**

*The Changing Face of Breast Cancer Care: A Focus on Biosimilar Monoclonal Antibodies*

1. **[Congress-Specific Statement – not always necessary]**

*14th St Gallen International Breast Cancer Conference 2015*

1. **[Date/Time---Please do not use AM or PM for Ex-US projects]**

Thursday, 19 March 2015

18.15–19.45

1. **[Location]**

Hall ABC

Austria Center Vienna

Bruno-Kreisky-Platz 1

A-1220 Vienna, Austria

1. **[Meeting Overview (or Statement of Need (if PIM is CME provider)]:**

**Symposia:**

We are pleased to invite you to our satellite symposium, The Changing Face of Breast Cancer Care: A Focus on Biosimilar Monoclonal Antibodies, to be held on 19 March 2015 at the 14th St Gallen International Breast Cancer Conference in Vienna, Austria.

1. **[Travel Grant Statement]**

For available travel grants, please contact travelgrants@prIMEoncology.org.

1. **[Target Audience]**

This educational activity is specifically designed for oncologists and other healthcare professionals involved in the treatment of patients with breast cancer.

1. **[Learning Objectives]**

After successful completion of this educational activity, participants should be able to:

* Describe the current management of patients with HER2+ breast cancer
* Explain the differences between biologics, biosimilars, and small-molecule medicines in terms of manufacture, development, and approval
* Identify key issues surrounding biosimilar monoclonal antibodies for the treatment of breast cancer

***[NOTE: learning objectives must be specific, measurable, attainable, relevant, time limited]***

1. **[Faculty Listing---note bolding and lack of colons, alphabetical order]**

**Chair**

Christian Jackisch, MD, PhD

Klinikum Offenbach

Offenbach, Germany

**Faculty**

Paul Declerck, PharmD, PhD

KU Leuven

Leuven, Belgium

Peter Schmid, MD, PhD, FRCP

Barts Cancer Institute

Queen Mary University of London

London, United Kingdom

1. **[Agenda]**

Insert agenda here, following this style format (note the bolding, unbolding, and italics):

**Thursday, 19 March**

18.15 Welcome and introduction

18.20 Update on the management of HER2+ breast cancer

*Christian Jackisch, MD, PhD*

18.45 Current landscape of biosimilars

*Paul Declerck, PharmD, PhD*

19.10 Special considerations for biosimilars in breast cancer

*Peter Schmid, MD, PhD, FRCP*

19.35 Q & A

19.45 Adjourn

1. **Provider**

This activity is provided by prIME Oncology.

1. **[Continuing Education---choose one]**

***[ACCME NOTE: The accreditation statement must appear on all CME activity materials and brochures distributed by accredited organizations, except that the accreditation statement does not need to be included on initial save-the-date type activity announcements. Such announcements contain only general, preliminary information about the activity such as the date, location and title. If more specific information is included, such as faculty and objectives, the accreditation statement must be included]***

**No CME**

Do not include a Continuing Education Statement.

\*\*All CME/CE verbiage should receive final approval from Regulatory/Compliance Manager

1. **Support Statement [ACCME—consult Cindy for proper verbiage and defer to BD for final approval of complete verbiage]**

This educational activity is supported by F. Hoffmann-La Roche Ltd.

1. **[Registration/Fee Information]**

There is no fee for this activity and preregistration is not required.

1. **[Disclosures---can be in much smaller font if necessary]**

**No CME**

**Flyer**

Disclosure of Relevant Financial Relationships

prIME Oncology assesses relevant financial relationships with its instructors, planners, managers, and other individuals who are in a position to control the content of activities. Any potential conflicts of interest that are identified are thoroughly vetted by prIME Oncology for fairness, balance, and scientific objectivity of data, as well as patient care recommendations. prIME Oncology is committed to providing its learners with high-quality activities and related materials that promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial entity.

Disclosure Regarding Unlabeled Use

This activity may contain discussion of published and/or investigational uses of agents that are not indicated by the US Food and Drug Administration or European Medicines Agency. Please refer to the official prescribing information for each product discussed for discussions of approved indications, contraindications, and warnings.

Disclaimer

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients’ conditions and possible contraindications or dangers in use, review of any applicable manufacturer’s product information, and comparison with recommendations of other authorities.

**Summary Book**

Disclosure of Relevant Financial Relationships

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The faculty reported the following financial relationships or relationships to products or devices they or their spouses/life partners have with commercial interest related to the content of this activity:

Dr Declerck has disclosed that he has received speakers’ fees and/or honoraria from Abbvie, Amgen, Celltrion, Hospira, Merck-Serono, Novo Nordisk, and Roche. He has agreed to disclose any unlabeled/unapproved uses of drugs or products referenced in his presentation.

Dr Jackisch has disclosed that he has ……………………………….. He has agreed to disclose any unlabeled/unapproved uses of drugs or products referenced in his presentation.

Dr Schmid has disclosed that he has ……………………………….. He has agreed to disclose any unlabeled/unapproved uses of drugs or products referenced in his presentation.

The employees of prIME Oncology have disclosed:

* Bojana Pajk, MD, MSc (medical content reviewer/planner) – no relevant financial relationships
* Trudy Stoddert, ELS (clinical content reviewer) – no relevant financial relationships

Disclosure Regarding Unlabeled Use

This activity may contain discussion of published and/or investigational uses of agents that are not indicated by the US Food and Drug Administration or European Medicines Agency. Please refer to the official prescribing information for each product discussed for discussions of approved indications, contraindications, and warnings.

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1. **[Welcome/Chair Letter] used for invitation and/or email blast**

Welcome Letter

Dear Colleagues,

Welcome to Vienna and the 14th St Gallen International Breast Cancer Conference 2015.

We are very pleased that you have chosen to attend this prIME Oncology satellite symposium, *The Changing Face of Breast Cancer Care: A Focus on Biosimilar Monoclonal Antibodies*. Through this educational activity, we aim to provide you with an overview on the development of biosimilar monoclonal antibodies for the treatment of breast cancer and how these new treatments may fit into the evolving armamentarium for breast cancer care. We hope you find the unique format of our symposium informative and engaging.

We appreciate your attendance and welcome your active participation.

Christian Jackisch, MD, PhD

Klinikum Offenbach

Offenbach, Germany

1. **[Back Page Copy] used for invitation and/or summary books**

EU Office

prIME Oncology

Schenkkade 50, Suite 16

2595 AR The Hague

the Netherlands

tel + 31.70.3067.190

About prIME Oncology

prIME Oncology is a global **pr**ofessional **I**ndependent **M**edical **E**ducation organization specializing in educational activities for physicians who treat patients with cancer. With the ultimate goal of improving patient outcomes, prIME Oncology provides evidence-based, state-of-the-art educational activities that assist oncology clinicians in making up-to-date and appropriate treatment decisions.

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PB5LSS023

1. **[URL and Mobile App Name---give suggestions for URL name] \*\*\*Should be discussed and decided upon at the Kickoff Meeting.**

Insert URL here.

www.prIMEoncology.org/Biosimilars\_Vienna2015

Program Book: www.prIMEoncology.org/Biosimilars\_Vienna2015\_Webcast

Insert Mobile App Name (restricted to 23 characters, including spaces. Conference names and abbreviations [ie, ASCO, ISHL] are appropriate to use. Do not include the location or year in the title. For Web activities, it is not necessary to include the type of activity [ie, CSP, Expert Review] in the title, as this will be indicated below the title. For Webcasts, use the same app title as was used for the live activity): St Gallen Biosimilars

1. **[Subject Line for Email Blast]**

A. Join Us in Vienna for A Focus on Biosimilar Monoclonal Antibodies in Breast Cancer

B. Register Now for a Symposium on Biosimilars – 18 March in Vienna

1. **[Email Blast Copy]**

Either list parts above that are to be included in the email blast or insert new (different) copy that is to be used in the email blast.

Example:

Title

Date/Time

Faculty

Topics

Target Audience

Learning Objectives

Providership (with logos)

Support (with logos)

1. **[Registration Confirmation Copy]**

Insert Registration Confirmation Email copy here.

Thank you for registering for *The Changing Face of Breast Cancer Care: A Focus on Biosimilar Monoclonal Antibodies,* a satellite symposium at the 14th St Gallen International Breast Cancer Conference 2015.

Thursday, 19 March 2015

18.15-19.45

Hall ABC

Austria Center Vienna

Bruno-Kreisky-Platz 1

A-1220 Vienna, Austria

Please do not hesitate to contact us should you require any further information.

Kind regards,

Saskia Speth

prIME Oncology

EU office: +31 70 30 67 190

Fax: +31 70 33 18 335

Email: [Saskia.Speth@prIMEoncology.org](mailto:Saskia.Speth@prIMEoncology.org)

1. **[Registration Confirmation Copy]**

You have cancelled the registration process. None of your information has been captured. To register, please return to the meeting home page.

If you experience difficulty registering, please contact the meeting organizer at info@prIMEoncology.org.

1. **[Other]**

Please add any additional copy needed but not listed above with a description of what it is and where it is needed.

**WEB REQUIREMENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Name (internal)** |  | **Project Code** |  |
| **Virtual Project Manager** | Choose an item. | **Clinical Program Manager** | Choose an item. |
| **Compliance** | Choose an item. | **Editor** | Choose an item. |

**Launch Date/Internal Launch Date:**

**Project Type**

Webcast

Downloadable Slides

CD/DVD

Podcast

Other:

**Email Blast Included?**

Yes

No

Subject Line:

**Number of E-Blasts**

Only One

Two

Three  
Other Amount:

Dates to Blast or Special Requests:

**Cross Promotion**

Yes

No

If Yes, List Activities:

**Target Audience**

US  
EX-US  
Global (Both EX-US & US)  
Other or Special:

Additional Emails (Supporters?):

**Slides**

Slides Included

Yes

No

Slide Location:

Slides Available By:

**Slides Synched? (if included in webcast)**

Yes

No

**Webpage Content (All Copy)**

Content Status (Final/Approved):  
  
Content Available by:

**CME?**

Yes

No

**CME Posttest Link:**

**Webcast/PDS URL:**

**Additional Components**

Cases with Voting

Polls

Video Segmentation

Table of Contents

Other:

**Mobile App Title:**

**LIVE MEETING-ASSOCIATED VIRTUAL ACTIVITIES**

1. **[Meeting-Associated Downloadable Slides]---VERIFY with Clinical after the meeting to see what presentation are to be included**

**Downloadable Slides From [Insert Meeting Title]**

**ACTIVITY FEATURES**

[Icon] Downloadable Slides

[Insert screen shot]

**ACTIVITY OVERVIEW**

prIME Oncology invites you to view Downloadable Slides from the [title] symposium/meeting [choose one] held in San Diego, California, United States.

\*\*\*May add a “in conjunction with \_\_\_\_\_\_\_” phrase if this is from a symposium at a congress.

**PROVIDER**

This activity is provided by prIME Oncology.

**[Tab—Insert Disease Topic]**

Discussant: **Name, Degree,** Institute, City, State, Country

Topic: Insert agenda topic

Learning Objective: Insert presentation-specific objective

[insert divider line]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Discussant: **Name, Degree,** Institute, City, State, Country

Topic: Insert agenda topic

Learning Objective: Insert presentation-specific objective

[insert divider line]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Discussant: **Name, Degree,** Institute, City, State, Country

Topic: Insert agenda topic

Learning Objective: Insert presentation-specific objective

[insert divider line]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Discussant: **Name, Degree,** Institute, City, State, Country

Topic: Insert agenda topic

Learning Objective: Insert presentation-specific objective

[insert divider line]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **[Meeting-Associated Webcast]---VERIFY with Clinical after the meeting to see what presentation are to be included**

**Insert Meeting Title**

**ACTIVITY FEATURES**

[Icon] Interactive Presentation

[Icon] Downloadable Slides

[Icon] Podcast (if appropriate)

[Icon] CME-Certified (if appropriate)

**ACTIVITY OVERVIEW**

This [CME-certified (if appropriate)] Webcast contains **video and downloadable slides** from the symposium/meeting [choose one] [Meeting Title], a prIME Oncology educational activity that was held on [insert date], in [insert location].

**TOPICS**

[Insert Agenda topic]

[*Insert presenter name and degree(s)]*

[Insert Agenda topic]

[*Insert presenter name and degree(s)]*

[Insert Agenda topic]

[*Insert presenter name and degree(s)]*

**FACULTY**

**Name, degree(s)**

Institution

City, State, Country

**Name, degree(s)**

Institution

City, State, Country

**Name, degree(s)**

Institution

City, State, Country

**TARGET AUDIENCE**

Insert target audience from live meeting

**LEARNING OBJECTIVES**

Insert objectives from live meeting [check with Clinical to see if any need to be deleted]

**CONTINUING MEDICAL EDUCATION [if applicable]**

prIME Oncology is accredited by the Accreditation Council for Continuing Medical Education (ACCME®) to provide continuing medical education for physicians.

prIME Oncology designates this live activity for a maximum of XX *AMA PRA Category 1 Credits™.* Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**METHOD OF PARTICIPATION [if applicable]**

There are no fees for participating in and receiving CME credit for this activity. In order to receive credit, participants must successfully complete the online post test and activity evaluation. Your participation in this CME activity will be recorded in prIME Oncology's database. However, upon request, your CME credit certificate will be emailed to you. Technical requirements may be found under the [Terms of Use.](http://www.primeoncology.org/footer-e-pages/terms_of_use.aspx)

Links to the posttest are available on the video player pages.

In order to receive credit, participants must successfully complete the online posttest with XX% or higher.

**DISCLOSURES [if applicable]**

Insert disclosure info from the live meeting.

**PROVIDER**

This Webcast is provided by prIME Oncology.

**SUPPORTER**

Insert supporter statement from live meeting.

**ACTIVITY DATE**

Release Date

Expiration Date

**MOBILE APP VIEW ACTIVITY TEXT PER VIDEO**Insert presentation-specific text for the “View Activity” action item on the mobile app.

1. **Web Activity Page Titles**

Landing Page Title:  
Activity Page Title:

1. **Meta Description  
   (One description for each page (including landing pages and all activity pages.** This should be roughly 150 characters in length. This is the short description that will appear beneath the activity title in search results, so it should be a compelling, keyword-rich description that will encourage the user to click)
2. **Key Words and Key Phrases  
   (Please included as many key words or phrases as are associated with the activity. 15 or more is ideal. These are words or phrases that a viewer might use in a web search. Please add one key word/phrase per line) Example:***squamous cell nsclc  
   nsclc mutations  
   egfr mutations in nsclc  
   lung cancer nsclc  
   etc*
3. **[Meeting-Associated Podcast]---VERIFY with Clinical after the meeting to see what presentation are to be included**

For each presentation:

Listing: City—Disease—Presenter

Description: [Name, degree(s)], from [Institution] discusses [insert topic description].