AEREON CONSULTING & PHARMA SERVICES ANNOUNCES THE

2ND MASTERCLASS RESPIRATORY TRIALS 2016

SUPPORTED BY INSAF RESPIRATORY RESEARCH INSTITUTE

€ 250 EARLY BIRD DISCOUNT on registration fee until 15-JANUARY-2016

AEREON CONSULTING & PHARMA SERVICES

insaf Respiratory Research Institute

BACKGROUNDER:

Asthma and COPD are common chronic disorders with high global burden of morbidity and mortality. The respiratory market for pharmaceuticals is expected to grow substantially in the upcoming years, making the area an attractive field for therapeutic developments. The design of clinical trials is pivotal for the development of any new drug, including the appropriate choice of patient populations, endpoints, methodology, and comparator treatments. With the landscape becoming more competitive and in light of increasing demands from health technology bodies, the challenge of successful market access for new therapeutics from molecule to practical application is ever growing.

TOPICS:

Learn the fundamentals of clinical trial design in asthma and COPD. Understand basic lung anatomy and respiratory physiology, as well as key methods to evaluate outcomes in trials including objective assessments and PROs. Get familiar with current treatment strategies and unmet clinical needs. Identify challenges in choices of study populations, trial design and outcomes. Learn of regulatory requirements for drug approval and the growing impact of HTA processes on drug reimbursement. Understand the environment of HTA in Europe and get familiar with the most recent experience with the national German process of early post-marketing value assessment (AMNOG). Enjoy a hands-on practical session for relevant respiratory outcome measures including spirometry, plethysmography, and exercise testing.

WHO SHOULD ATTEND?

Industry Executives, Officers, Scientist, Project Leaders, etc. involved in Respiratory Medicine or Pharmacology, Therapeutic Development, Medical Sciences, R&D, Market Access etc.

YOUR SPEAKERS:

The involved speakers sum up experience of over 15 years in respiratory clinical research, with more than 100 trials planned, designed and conducted. External speaker(s) are renowned international experts in the field of asthma and COPD.

AGENDA 2ND MASTERCLASS RESPIRATORY

DAY 1	18TH MARCH 2016	
10.30 – 10.45	Welcome and Introduction	(All)
10.45 – 11.30	Respiratory Anatomy and Airway Pathology	(Beier)
11.30 – 13.00	Clinical Methodology in Respiratory Medicine *Pulmonary Function Testing, Challenge Models, Airway Monitoring etc.*	(Beeh)
13.00 – 14.00	Lunch	
14.00 – 14.45	Asthma Clinical Background *Epidemiology, Treatment Strategies (GINA), Unmet Needs*	(N.N.)
14.45 – 15.30	COPD Clinical Background *Epidemiology, Treatment Strategies (GOLD), Unmet Needs*	(N.N.)
15.30 – 16.15	PROs in Asthma and COPD Trials, Part 1: *Regulations, Applications, Limitations – Examples*	(Beier)
16.15 – 16.30	Afternoon Coffee Break	
16.45 – 17.15	PROs; Part 2:. *What is "meaningful ?" Issues around MCIDs*	(Beeh)
17.15-17.30	Q/A, Discussion	(All)
17.30	End of Day 1	
19.00	Meeting for Dinner at "Käfer's Bistro", Wiesbaden	(All)

Venue:
Dorint Hotel Wiesbaden /
insaf Respiratory Research Institute,
Biebricher Allee 34,
D-65187 Wiesbaden, Germany

Time:
10.30 – 17.30 h (Day 1)
09.00 – 17.30 h (Day 2)
09.15 – 12.30 h (Day 3)

Date:
18th MAR 2016 – 20th MAR 2016

TRIALIST 2016 THREE DAY COURSE

DAY 2	19TH MARCH 2016	
06.30 – 09.00	Breakfast	
09.00 – 10.15	Clinical Trials Design (Patients, Outcomes etc.): *Asthma*	(Beier)
10.15 – 10.30	Coffee Break	
10.30 – 12.00	Clinical Trial Design (Patients, Outcomes etc.): *COPD*	(Beeh)
12.00 – 12.45	Impact of HTA – de facto 4th Hurdle? *European Perspective*	(Beeh)
12.45 – 13.45	Lunch	
13.45 – 14.30	"AMNOG" Benefit Assessment in Germany *Implications for Trial Design and Experience with Respiratory Drugs*	(Beeh)
14.30 – 15.15	Practice Session	(All)
15.15 – 16.15	Practical Case Study: *Asthma*	(All)
16.15 – 16.30	Afternoon Coffee Break	
16.30 – 17.30	Practical Case Study: *COPD*	(All)
17.30	Summary and Discussion	(All)
	End of Day 2	

DAY 3	20TH MARCH 2016	
06.30 – 09.00	Breakfast	
09.15 – 10.30	Practical Breakout Session Part 1 (at insaf Research Site) *a) Spirometry* *b) Whole-body plethysmography* *c) Exercise testing*	(All)
10.30 – 10.45	Coffee Break	
10.45 – 12.00	Practical Breakout Sessions (Asthma) *a) Airway Challenge Models* *b) Skin Testing and exhaled NO Monitoring*	(All)
12.00 – 12.30	Roundup Summary and Conclusion, Certification	(All)
13.00	Lunch and Departure	

REGISTRATION:

€ 250 EARLY BIRD DISCOUNT on registration fee until 15-JANUARY-2016

Registration via

- masterclass2016@aereon.de
- Fax +49 611 9854348

Registration form:

☐ I hereby sign up to the 2nd "Masterclass Respiratory Trials 2016"

Name/First Name .....

Position/Department .....

Company .....

Street Address .....

City, ZIP Code .....

Country .....

Phone .....

E-Mail .....

Date, Signature .....

Costs: 2950,– EUR (excl. VAT)

Early Bird Registration Fee 2700,– EUR (excl. VAT) for registrations until 15th JAN 2016 !

Package for full 3 days course includes:

- Course registration and learning materials
- Hotel accommodation (Dorint Pallas Wiesbaden) for 2 nights including breakfast
- Lunch Buffet and Coffee break Day 1, Day 2 and Day 3
- Get-together dinner evening Day 1

Minimum of 5 participants/registrations required, maximum 12 participants.

Internet: www.aereon.de
Date / Venue: Friday, 18th March 2016 – Sunday 20th March 2016.

Dorint Pallas Hotel Wiesbaden
Auguste-Viktoria-Str. 15
65185 Wiesbaden
www.hotel-wiesbaden.dorint.com
Phone +49 611 3306-0

insaf Respiratory Research Institute
Biebricher Allee 34
65187 Wiesbaden
www.insaf-wi.de
Phone +49 611 9854410

Directions:
Dorint Hotel and insaf Institute are located in the heart of Wiesbaden, the capital of the federal state of Hesse, within walking distance of Wiesbaden central train station and only a 15 minute car ride from **International Airport Frankfurt/Rhine-Main (FRA).**

Terms and Conditions
Our general terms and conditions apply (as of 01.03.2015), which we will send upon request and can be also be found on www.aereon.de.

Any enquiries should be directly addressed to:
Kai M. Beeh, Chairman MasterClass 2016
k.beeh@aereon.de
Phone: +49 611 9854347