Basilea and Astellas update isavuconazole phase III trial in consultation with FDA

Basel, Switzerland, November 26, 2010 - Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that in consultation with the U.S. Food and Drug Administration (FDA) Basilea and its partner Astellas Pharma Inc. have agreed to use ‘all-cause mortality’ as the primary endpoint of the phase III clinical study investigating isavuconazole for the treatment of invasive aspergillosis. The company confirms the previously communicated timelines for the ongoing phase III program.

All-cause mortality, which was one of the secondary study endpoints, will become the primary endpoint of the phase III clinical trial investigating isavuconazole in invasive aspergillosis. The total target number of patients will be around 510 in the study. The previous primary outcome measure of ‘overall response’ (clinical, mycological and radiological response) will continue to be assessed in the study as a secondary endpoint.

“It is important that development programs keep up with scientific advances and take into account current regulatory thinking. We will continue to assess the overall response as a secondary endpoint to obtain a comprehensive clinical profile of this novel drug,” said Professor Achim Kaufhold, M.D., Chief Medical Officer of Basilea. “The change in primary endpoint does not have any impact on our ongoing preparations to restart the isavuconazole phase III program as the operational aspects of the way the study is conducted remain unchanged.”

This decision does not affect the previously communicated timelines for the ongoing phase III program of isavuconazole. Initiation of first sites is anticipated at year-end or early 2011 and the availability of phase III results continues to be expected in 2013.

About isavuconazole

Pre-clinical and clinical data generated to date indicate that isavuconazole has the potential to overcome many limitations of current therapies for the treatment of invasive fungal infections. Isavuconazole is given by intravenous infusion or oral capsules with high oral bioavailability that provides an option for intravenous-oral step-down. The drug has predictable and dose proportional pharmacokinetics that are important to ensure adequate therapeutic drug levels in patients with life-threatening fungal infections. The intravenous dose form has the potential to be given safely to patients with renal impairment.

The clinical program includes three international phase III trials with centers in the U.S., Europe and other regions that target respectively, yeast infections (candidemia/invasive Candida infections), mold infections (invasive aspergillosis) and finally rare molds and aspergillosis in renally impaired patients.

Earlier this year, an Independent Data Safety Monitoring Board recommended continuation of the phase III clinical trial of isavuconazole for the treatment of invasive Aspergillus infections based on a futility analysis of the first 180 patients. Isavuconazole has been granted fast track designation by the U.S. Food and Drug Administration (FDA).
Conference call
Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Friday, November 26, 4 p.m. (CET), during which the company will discuss today's press release.

Dial-in numbers are:
+41 (0) 91 610 56 00 (Europe and ROW)
+1 (1) 866 291 4166 (USA)
+44 (0) 203 059 5862 (UK)

A playback will be available 1 hour after the conference call until Tuesday, November 30, 6 p.m. (CET). Participants requesting a digital playback may dial:
+41 (0) 91 612 4330 (Europe)
+1 (1) 866 416 2558 (USA)
+44 (0) 207 108 6233 (UK)
and will be asked to enter the ID 10406 followed by the # sign.

About Basilea
Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX:BSLN). Its fully integrated research and development operations are currently focused on antibiotics, antifungals and oncology drugs, as well as on the development of dermatology drugs, targeting the medical challenge of resistance and non-response to current treatment options in the hospital and specialty care setting.

Basilea is currently marketing Toctino® (alitretinoin), the only approved treatment for severe chronic hand eczema unresponsive to potent topical corticosteroids, in Denmark, France, Germany, Switzerland and the United Kingdom and has appointed distributors for Toctino® in other selected European markets, Canada and Mexico. Furthermore, a phase III clinical program on alitretinoin for the treatment of severe chronic hand eczema is ongoing in the U.S. The company has entered into a global partnership with Astellas Pharma Inc. for its phase III compound isavuconazole, a potential best-in-class azole antifungal, for the treatment of life-threatening invasive fungal infections. Full rights to ceftobiprole for the treatment of potentially life-threatening resistant bacterial infections, are being transferred from Cilag GmbH International, a Johnson & Johnson company, back to Basilea.

About Astellas
Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 16,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. Astellas has discovered a treatment for over-active bladder (OAB), Vesicare® and an immunosuppressant, Prograf® (tacrolimus), which have enabled Astellas to become an established leader in both urology and transplant. For more information on Astellas Pharma Inc., please visit www.astellas.com/en.

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as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For further information, please contact:

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This press release can be downloaded from www.basilea.com