



Avillion Announces Completion of Enrolment in Phase III BFORE Trial to Assess BOSULIF® (bosutinib) as First-Line Treatment for Patients with Chronic Myelogenous Leukemia

London, UK, September 15, 2015 – Avillion LLP, a co-developer of late-stage pharmaceutical assets, announces the completion of enrolment in a global Phase III clinical trial called “BFORE,” which is designed to assess the effectiveness and safety of BOSULIF® (bosutinib) as a first-line treatment for patients with chronic phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML). The first patient was dosed on July 22, 2014 and the final patient was enrolled September 8,, 2015.

Avillion enrolled 536 patients into the BFORE (Bosutinib trial in First line chrOnic myelogenous leukemia tREatment) trial at multiple sites in the United States, Asia and Europe. The trial is a Phase III, two-arm, randomized, open label trial. Patients were randomized 1:1 to receive bosutinib or imatinib for the duration of the study (ClinicalTrials.gov Identifier: NCT02130557). The primary outcome was to show superiority of bosutinib over imatinib at 12 months by comparing the proportion of patients in each arm whose levels of the Bcr-Abl1 kinase, the target for bosutinib, have dropped below 0.1%.

Dr Tim Brummendorf MD, European lead Investigator, based at Universitätsklinikum Aachen, (Aachen, Germany), said: “I am pleased to announce the successful completion of patient recruitment in the BFORE study, a target which has been achieved efficiently and well within the initially proposed patient-accrual timelines. I would like to extend the gratitude of the study team to all of the investigators and site staff who worked so diligently to identify and randomise patients in the study, and to thank them in advance for their continued hard work in the core phase of study, and in the follow-up period.”

On January 9, 2014, Avillion announced it had entered into an exclusive collaborative development agreement with Pfizer Inc. to conduct a global Phase III clinical trial of BOSULIF®. Under the terms of the agreement, Avillion is providing all of the funding for and is conducting the trial to generate the clinical data necessary to potentially support a registration dossier for marketing authorization of BOSULIF® by regulatory authorities as first-line treatment of patients with chronic phase Ph+ CML. If approved for this indication, Avillion will be eligible to receive milestone payments from Pfizer upon regulatory approval of the drug. Pfizer retains all rights to commercialize BOSULIF® globally.

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About BOSULIF®

BOSULIF® (bosutinib) is an oral, once-daily tyrosine kinase inhibitor (TKI), which inhibits the Bcr-Abl kinase that promotes CML; it is also an inhibitor of Src-family kinases. BOSULIF® is currently approved in the U.S. for the treatment of adult patients with Ph+ CML with resistance or intolerance to prior therapy and offers an important treatment option for these patients. In Europe, BOSULIF® was granted conditional marketing authorization for the treatment of adult patients with Ph+ CML



previously treated with one or more TKIs and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

About Avillion

Avillion LLP is a drug development company with an innovative business model focusing on the clinical development and regulatory approval of late stage pharmaceutical products. Avillion LLP offers a compelling opportunity to partner late-stage therapeutic projects for approval in the US and EU and to accelerate their availability to the market. Our objective is to enable our partners to continue to develop the drug candidates in their pipeline at the highest quality without increasing the burden on their P&L or cash reserves. Avillion LLP can achieve this by incurring 100% of the clinical and regulatory risk, while advancing the development of these late-stage assets.

Avillion was founded in 2012 in London, UK, and is backed by Abingworth, Clarus Ventures and Royalty Pharma. www.avillionllp.com

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