



Avillion Announces Dosing of First Patients in Phase 3 BFORE Trial to Assess BOSULIF® (bosutinib) as First-Line Treatment for Patients with Chronic Myelogenous Leukemia

London, UK, August 11, 2014 – Avillion LLP, a co-developer of late-stage pharmaceutical assets, announces that the first patients have been dosed in the United States in a global Phase 3 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.

On January 9, 2014, Avillion announced it had entered into an exclusive collaborative development agreement with Pfizer Inc. to conduct a global Phase 3 clinical trial of BOSULIF®. Under the terms of the agreement, Avillion is providing the funding for and will conduct 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 will retain all rights to commercialize BOSULIF® globally.

Avillion intends to enrol approximately 530 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 3, two-arm, randomized, open label trial. Patients will be randomized 1:1 to receive bosutinib or imatinib for the duration of the study (ClinicalTrials.gov Identifier: NCT02130557). The primary outcome is 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 Jorge Cortes MD, Co-ordinating Investigator, based at MD Anderson Cancer Center (Houston, TX, USA), said: “The first patients dosed marks an important milestone on a study that we hope will confirm the results that we all expect, namely, a superior outcome with bosutinib compared to imatinib in this patient population. If the study results in such superiority, bosutinib could become a welcome new frontline treatment option for patients with CML for whom few treatment options currently exist.”

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 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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