Avillion notes that Pfizer Received a Positive CHMP Opinion for BOSULIF® (bosutinib) for Treating Newly-Diagnosed Ph+ Chronic Myelogenous Leukemia

Filing based on the successful BFORE Phase 3 study conducted by Avillion under a collaborative development agreement with Pfizer

London, UK, February 23, 2018 – Avillion, a drug development company focused on the co-development and financing of pharmaceutical candidates from proof-of-concept through to regulatory approval, notes today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending that Pfizer's BOSULIF® (bosutinib) be granted marketing authorisation in the European Union (EU).

BOSULIF® (bosutinib) has been granted a positive opinion for the treatment of adults with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). The CHMP's opinion will now be reviewed by the European Commission (EC).

BOSULIF currently has conditional marketing authorisation in Europe related to the initial marketing authorisation. The Type II Variation application for BOSULIF for adults with newly diagnosed chronic phase Ph+ CML was based on results from BFORE (Bosutinib trial in First line chrOnic myelogenous leukemia tREatment), a randomized, multicentre, multinational, open-label, Phase 3, head-to-head study of BOSULIF 400 mg versus imatinib 400 mg, a current standard of care.

Pfizer and Avillion entered into an exclusive collaborative development agreement in 2014 to conduct the BFORE trial. Under the terms of the agreement, Avillion provided funding for the trial to generate the clinical data used to support this application and other potential regulatory filings for marketing authorization for BOSULIF as first-line treatment for patients with chronic phase Ph+ CML. Pfizer retains all rights to commercialize BOSULIF globally.

The Pfizer announcement can be found by clicking here.

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About Avillion
Avillion is a drug development company with an innovative business model focusing on the clinical co-development and regulatory approval of pharmaceutical products. Avillion offers a compelling opportunity to partner assets from post proof-of-concept through to regulatory approval globally and to accelerate their development and hence availability to patients. Avillion's objective is to enable its partners to continue to develop the drug candidates in their pipeline whilst maintaining quality data without increasing the burden on their P&L or cash reserves. Avillion can achieve this by incurring 100% of the clinical and regulatory risk, while advancing the development of these assets in return for milestone and royalty payments on the commercialisation of successfully developed products.

To date, Avillion has advanced Pfizer's BOSULIF® (bosutinib) successfully through Phase 3 trials and provided the clinical data used to gain US approval to expand its use to include patients with newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukaemia.

Avillion is also undertaking Phase 2 trials with Merck's anti IL-17 A/F Nanobody® in plaque psoriasis.

Avillion was founded in 2012, and is backed by Abingworth, Clarus Ventures and Royalty Pharma.

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"Avillion" is Bond Avillion 2 Development LP.

Important BOSULIF® (bosutinib) Safety Information from the U.S. Prescribing Information
Contraindication: History of hypersensitivity to BOSULIF. Reactions have included anaphylaxis. Anaphylactic shock occurred in less than 0.2% of treated patients in single-agent cancer studies with BOSULIF.

Gastrointestinal Toxicity: Diarrhea, nausea, vomiting, and abdominal pain can occur. In the randomized clinical trial of patients with newly diagnosed Ph+ CML, the median time to onset for diarrhea (all grades) among patients in the BOSULIF treatment group (n=268) was 3 days and the median duration per event was 3 days. Among 546 patients in a single-arm study of patients with CML who were resistant or intolerant to prior therapy, median time to onset of diarrhea (all grades) was 2 days, median duration was 2 days, and the median number of episodes per patient was 3 (range 1-268). Monitor and manage patients using standards of care, including antidiarrheals, antiemetics, and/or fluid replacement. Withhold, dose reduce, or discontinue BOSULIF as necessary. Myelosuppression: Thrombocytopenia, anemia, and neutropenia can occur. Perform complete blood counts weekly for the first month and monthly thereafter, or as clinically indicated. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Hepatic Toxicity: Elevations in serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) can occur. Perform hepatic enzyme tests at least monthly for the first 3 months and as clinically indicated. In patients with transaminase elevations, monitor liver enzymes more frequently. One case consistent with drug-induced liver injury occurred without alternative causes in a trial of BOSULIF in combination with letrozole. Withhold, dose reduce, or discontinue BOSULIF as necessary. In patients with mild, moderate, or severe hepatic impairment, the recommended starting dose is 200 mg daily.

Renal Toxicity: An on-treatment decline in estimated glomerular filtration rate has occurred in patients treated with BOSULIF. Monitor renal function at baseline and during therapy, with particular attention to patients with preexisting renal impairment or risk factors for renal dysfunction. Consider dose adjustment in patients with baseline and treatment-emergent renal impairment.

Reduce the BOSULIF starting dose in patients with moderate (creatinine clearance [CLcr] 30 to 50 mL/min) or severe (CLcr less than 30 mL/min) renal impairment at baseline. For patients who have declining renal function while on BOSULIF who cannot tolerate the starting dose, follow dose adjustment recommendations for toxicity.

Fluid Retention: Fluid retention can occur with BOSULIF and may cause pericardial effusion, pleural effusion, pulmonary edema, and/or peripheral edema. Among 546 patients in a single-arm study of patients with Ph+ CML who were resistant or intolerant to prior therapy, Grade 3/4 fluid retention was reported in 26 patients (5%). Monitor and manage patients using standards of care. Interrupt, dose reduce, or discontinue BOSULIF as necessary.

Embryofetal Toxicity: BOSULIF can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised of the potential hazard to the fetus. Advise females of reproductive potential to use effective contraceptive measures to prevent pregnancy while being treated with BOSULIF and for at least 1 month after the final dose.

Adverse Reactions: The most common adverse reactions observed in greater than or equal to 20% of patients with newly diagnosed CML were diarrhea, nausea, thrombocytopenia, rash, increased ALT, abdominal pain, and increased AST. The most common Grade 3/4 adverse reactions and laboratory abnormalities observed in greater than 10% of newly diagnosed CML patients were thrombocytopenia and increased ALT.

The most common adverse reactions observed in greater than or equal to 20% of patients with CML who were resistant or intolerant to prior therapy were diarrhea, nausea, abdominal pain, rash, thrombocytopenia, vomiting, anemia, fatigue, pyrexia, cough, headache, ALT, and edema. The most common Grade 3/4 adverse reactions and laboratory abnormalities observed in greater than 10% of patients who were resistant or intolerant to prior therapy were thrombocytopenia, neutropenia, and anemia.

CYP3A Inhibitors and Inducers: Avoid concurrent use with strong or moderate CYP3A inhibitors or strong CYP3A inducers.

Proton Pump Inhibitors: Use short-acting antacids or H2 blockers instead of PPIs to avoid a reduction in BOSULIF exposure. Separate antacid or H2 blocker dosing and BOSULIF dosing by more than 2 hours.

Lactation: Because of the potential for serious adverse reactions in a nursing child, breastfeeding is not recommended during treatment with BOSULIF and for at least 1 month after the last dose.

Please see full U.S. Prescribing Information for BOSULIF here.

About Chronic Myelogenous Leukemia (CML)
Chronic myelogenous leukemia (CML) is a rare blood cancer, which begins in the bone marrow, but often moves into the blood.[1] Researchers estimate that by 2020, more than 412,000 people worldwide will be diagnosed with leukemia (all types).[2] Across Europe, CML constitutes about 15% of all leukemia and occurs with an incidence of about 1-1.5/100,000.[3]

About BOSULIF® (bosutinib)
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. In the U.S., BOSULIF (bosutinib) is indicated for the treatment of adult patients with newly-diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial. BOSULIF is also indicated in the U.S for the treatment of adult

patients with chronic, accelerated or blast phase Ph+ CML with resistance or intolerance to prior therapy (first approved in September 2012).

In Europe, BOSULIF was granted conditional marketing authorization in March 2013 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.

1. American Cancer Society. What is Chronic Myeloid Leukemia? http://www.cancer.org/acs/groups/cid/documents/webcontent/003112-pdf.pdf. Accessed February 2018.
2. GLOBOCAN Online Analysis/Prediction. http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=12280&Text-c=Leukaemia&pYear=8&type=0&window=1&submit=%C2%A0Execute Accessed February 2018.
3. European Treatment and Outcome Study. https://www.eutos.org/content/registry/index_eng.html. Accessed February 2018.