

## Arix Bioscience plc

### Amlyx unveils expanded pipeline and reports Phase 2 data from lead programme

*Positive preliminary Phase 2 safety and efficacy data from lead programme APX001 (fosmanogepix)*

*Phase 2-ready programme for the treatment of BK virus infection licensed from Novartis*

LONDON, 17 September, 2019: Arix Bioscience plc (LSE:ARIX) ("Arix"), a global venture capital company focused on investing in and building breakthrough biotech companies, today notes the following updates from its portfolio company Amlyx Pharmaceuticals ("Amlyx"), a biotech company dedicated to developing innovative therapies for debilitating and life-threatening diseases in patients with compromised immune systems.

#### Positive preliminary data from ongoing APX001 (fosmanogepix) Phase 2 study in candidemia

Amlyx announced that two independent review committees completed their planned safety and efficacy assessment of data from 50% of the planned study population enrolled in its Phase 2 open-label clinical trial of APX001 (fosmanogepix) for the treatment of candidemia.

The Data Review Committee (DRC) and Data Safety Monitoring Board (DSMB) have reviewed data from the first ten patients. The DRC adjudicated that fosmanogepix demonstrated a high level of treatment success at the end of study drug treatment. Treatment success is defined as clearance of Candida from the blood, patient is alive following treatment, and having received no other systemic antifungal therapies following initiation of study drug. Following review of the safety data, the DSMB recommended that the study continue according to the protocol. The Phase 2 study will continue to enroll patients, with a planned total of 20 patients by the end of the year, across sites in the United States, Europe and Israel.

Ciara Kennedy, Ph.D., president and CEO of Amlyx commented:

"These initial clinical trial results represent the first efficacy data in patients and support the highly differentiated profile of fosmanogepix for the treatment of serious fungal infections, representing an important milestone for the fosmanogepix Phase 2 candidemia study."

The full press release is available here: <https://amlyx.com/amlyx-pharmaceuticals-announces-positive-preliminary-data-from-ongoing-fosmanogepix-phase-2-study-in-candidemia/>

#### Phase 2 drug candidate for BK viral disease in transplant patients licensed from Novartis

Amlyx announced that it has executed an exclusive worldwide license agreement with Novartis under which Amlyx has acquired the rights to the Phase 2 anti-BK virus (BKV) monoclonal antibody, MAU868, for the treatment and prevention of BKV disease. Financial terms have not been disclosed.

MAU868 is a potent neutralizing monoclonal antibody with activity against BKV, which is present in 80 to 90 percent of the population. BKV reactivation can occur following kidney transplantation and may result in BKV nephropathy, a leading cause of renal allograft loss. BKV reactivation also occurs in patients who have received hematopoietic stem cell transplants (HSCT) and can lead to hemorrhagic cystitis, a painful and potentially life-threatening inflammatory condition of the bladder. BKV disease can have devastating and costly consequences

in transplant patients. The company is planning two Phase 2 proof-of-concept clinical trials of MAU868 in BKV disease.

**Ciara Kennedy, Ph.D., president and CEO of Amplyx commented:**

"The addition of MAU868 to the Amplyx pipeline leverages the company's significant experience from fosmanogepix (APX001), currently in development for the treatment of life threatening invasive fungal infections, by providing novel treatments to the same patient populations and treating physicians. We anticipate starting Phase 2 trials in the near future and, longer term, developing MAU868 as the first antiviral drug for BKV disease."

The full press release is available here: <https://amplyx.com/amplyx-pharmaceuticals-licenses-phase-2-drug-candidate-for-bk-viral-disease-in-transplant-patients/>

[ENDS]

## Enquiries

For more information on Arix, please contact:

**Arix Bioscience plc**  
Charlotte Parry, Head of Investor Relations  
+44 (0)20 7290 1072  
[charlotte@arixbioscience.com](mailto:charlotte@arixbioscience.com)

**Optimum Strategic Communications**  
Mary Clark, Supriya Mathur  
+44 (0)203 714 1787  
[optimum.arix@optimumcomms.com](mailto:optimum.arix@optimumcomms.com)

## About Arix Bioscience plc

Arix Bioscience plc is a global venture capital company focused on investing in and building breakthrough biotech companies around cutting edge advances in life sciences.

We collaborate with exceptional entrepreneurs and provide the capital, expertise and global networks to help accelerate their ideas into important new treatments for patients. As a listed company, we are able to bring this exciting growth phase of our industry to a broader range of investors. [www.arixbioscience.com](http://www.arixbioscience.com)

## About Amplyx Pharmaceuticals

Amplyx Pharmaceuticals is focused on developing innovative therapies for patients with compromised immune systems, including cancer and transplant patients, and the critically ill. The company's two lead products are fosmanogepix (APX001) for the treatment of life-threatening fungal infections caused by pathogens such as Candida, Aspergillus and rare molds; and MAU868, a monoclonal antibody that potently neutralizes the BK virus which can cause significant morbidity and mortality in transplant patients. For more information, please visit [www.amplyx.com](http://www.amplyx.com)

## About Fosmanogepix

Fosmanogepix is currently in Phase 2 clinical trials evaluating the efficacy and safety of both IV and oral formulations for the first-line treatment of patients with fungal infections. Manogepix (APX001A), the active moiety of fosmanogepix (APX001), inhibits the highly conserved fungal enzyme Gwt1, compromising growth of fungal pathogens. The novel mechanism of action of fosmanogepix translates into a highly versatile drug that demonstrates activity against drug-resistant strains and can be delivered in both oral and intravenous

formulations. In multiple nonclinical studies, manogepix has shown broad-spectrum activity against common species of *Candida* and *Aspergillus*, including multi-drug resistant strains, such as *C. auris* and *C. glabrata*, as well as rare, hard-to-treat molds including *Fusarium*, *Scedosporium*, and fungi from the Mucorales order.

Invasive infections due to *Aspergillus*, *Fusarium*, *Scedosporium* and other rare molds are especially difficult to treat resulting in high mortality rates (50-80%), even when patients receive standard-of-care treatment. The frequency of fungi resistant to both the azole and echinocandin classes of drugs is increasing. Thus, there remains a significant unmet medical need for a new broad-spectrum antifungal to treat serious, invasive fungal infections and reduce the existing high morbidity and mortality.

#### **About BK Virus**

BK virus is one of 13 known polyomaviruses. Antibodies to BKV are found in approximately 80 to 90 percent of adults worldwide, indicating previous infection or exposure to the virus. Initial infection with BKV is usually asymptomatic or associated with a mild flu-like illness. After primary infection, BKV remains inactive, or latent, in kidney and bladder. A weakened immune system may result in BKV reactivation and cause serious disease. In patients who have had kidney transplant, BKV can lead to the loss of the transplanted kidney. In the absence of effective treatment, reduction of immunosuppression is recommended; however, lowering of the immunosuppression can lead to acute organ rejection. BKV reactivation in the bladder can cause hemorrhagic cystitis. Severe cases require bladder irrigation, clot evacuation, blood transfusion, stenting and nephrostomy. There are currently no approved treatments for renal nephropathy or hemorrhagic cystitis caused by BKV.

#### **About MAU868**

MAU868 is a novel human monoclonal antibody directed against the major viral capsid protein of BKV, VP1, which is essential for binding to and infection of new cells. MAU868 neutralizes all four genotypes of BKV at sub-nanomolar concentrations and has a high barrier to resistance *in vitro*. MAU868 also has neutralizing activity against the closely related JC virus, the cause of progressive multifocal leukoencephalopathy.