



Pfizer Acquires Amplyx Pharmaceuticals

Wednesday, April 28, 2021 - 06:45am

Deal expands anti-infectives pipeline with addition of novel antifungal Phase 2 candidate, Fosmanogepix (APX001)

Opportunity to advance Pfizer's expertise and deep heritage in infectious disease

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that it has acquired Amplyx Pharmaceuticals, Inc., a privately-held company dedicated to the development of therapies for debilitating and life-threatening diseases that affect people with compromised immune systems. Amplyx's lead compound, Fosmanogepix (APX001), is a novel investigational asset under development for the treatment of invasive fungal infections.

More than 1.5 million cases of invasive fungal infections occur worldwide each year, with mortality rates as high as 30-80% across infection typesⁱ. Fosmanogepix has a novel mechanism of action with the potential to target fungal strains resistant to standard of care therapy. As there are only three classes of antifungal medications currently available, antifungal resistance can severely limit treatment options; a potential new therapeutic class may therefore be of importance for both physicians and patientsⁱⁱ. There has been no novel therapeutic class of antifungal therapies approved by the U.S. Food and Drug Administration (FDA) in nearly 20 years.

"The COVID-19 pandemic has been a stark reminder of the devastating impact of infectious diseases, highlighting the continuous need for new anti-infective therapies to treat both emerging and difficult to treat bacterial, viral and fungal infections," said Angela Lukin, Global President, Pfizer Hospital. "We are deeply committed to helping patients suffering from infectious diseases, continuously seeking opportunities to build our portfolio of anti-infective therapies. We've already invested in assets that, if approved, could help address drug-resistant bacterial infections and critical viral

infections; with this acquisition, we look forward to progressing the development of a novel anti-fungal as well."

Fosmanogepix is currently in Phase 2 clinical trials evaluating the safety and efficacy of both intravenous (IV) and oral formulations for the treatment of patients with life-threatening invasive fungal infections caused by molds, yeasts and rare molds (e.g., *Aspergillus* spp, *Candida* spp including *Candida auris*, *Fusarium* spp. and *Scedosporium* spp). Fosmanogepix has demonstrated broad-spectrum activity invitro and has shown wide distribution to various tissues including the brain, lung, kidney and eye. With both IV and oral formulations in development, Fosmanogepix may allow for the transition from IV to oral, thus potentially enabling, for the benefit of patients, the continuation of treatment outside the hospital.

In addition to Fosmanogepix, with this acquisition, Pfizer has secured ownership of Amplyx's early-stage pipeline that includes potential antiviral (MAU868) and antifungal (APX2039) therapies.

Globally, infectious diseases are responsible for more than 8.4 million deaths annually^{*iii}, accounting for two of the World Health Organization's top ten causes of death worldwide^{iv}. Infections are caused by different types of pathogens, including bacteria, viruses, fungi and parasites, and can be acquired in the community or in a hospital or healthcare setting.

The acquisition of Amplyx follows an initial equity investment by Pfizer in December 2019 as part of Amplyx's Series C financing. At that time, Pfizer joined a world class group of biotechnology investors that included 3x5 Partners, Adage Capital Management, Aris Bioscience, BioMed Ventures, Lundbeckfonden Ventures, New Enterprise Associates, Pappas Capital, RiverVest Venture Partners and Sofinnova Investments.

Financial terms of this acquisition were not disclosed.

DLA Piper LLP (US) served as Pfizer Inc.'s legal advisor for the transaction, while Cooley LLP served as Amplyx's legal advisor and Evercore as its financial advisor.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across

developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

PFIZER DISCLOSURE NOTICE

The information contained in this release is as of April 28, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Amplyx Pharmaceuticals, Amplyx's lead compound, Fosmanogepix (APX001), the acquisition of Amplyx by Pfizer and Pfizer's anti-infectives portfolio that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things; risks related to the ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory.

actions related to the acquisition; other business effects, including the effects of industry, market, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; future business combinations or disposals; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for Fosmanogepix or

any other anti-infectives; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether Fosmanogepix or any such other anti-infectives will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Fosmanogepix or any such other anti-infectives; the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

* Excludes deaths attributed to COVID-19.

i Bongomin F et al J. Fungi 2017, 3, 57. Global and Multi-National Prevalence of Fungal Diseases-Estimate Precision. Available at: <https://pubmed.ncbi.nlm.nih.gov/29371573/>. Accessed April 2021.

ii Center for Disease Control and Prevention. Antifungal Resistance. Available at: <https://www.cdc.gov/fungal/antifungal-resistance.html>. Accessed April 2021.

iii Global Burden of Disease Tool [Data set], University of Washington, Institute for Health Metrics and Evaluation, Global Health Data Exchange, 2020. Available at: <http://ghdx.healthdata.org/gbd-resultstool>. Accessed April 2021.

iv World Health Organization. Top 10 Causes of Death. Available at: <https://www.who.int/en/newsroom/fact-sheets/detail/the-top-10-causes-of-death>. Accessed April 2021.

View source version

on businesswire.com: <https://www.businesswire.com/news/home/20210428005147/en>

Pfizer Inc.

Media Contact:

Eamonn Nolan

+1 (212) 733-4626

Eamonn.Nolan@Pfizer.com

Investor Contact:

Chuck Triano

+1 (212) 733-3901

Charles.E.Triano@Pfizer.com

Source: Pfizer Inc.