Pfizer Goes To Court To Allow Competition For Biologics And Expand Options For Patients

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To ensure patients and providers have access to important, lower cost biosimilar medicines, Pfizer (NYSE:PFE) today filed suit in the U.S. District Court for the Eastern District of Pennsylvania against Johnson & Johnson (J&J).

The suit alleges that J&J's exclusionary contracts and other anticompetitive practices have denied U.S. patients access to therapeutic options and undermined the benefits of robust price competition in the innovative and growing biologics marketplace for patients. It further claims that J&J's systematic efforts to maintain its monopoly in connection with Remicade® (infliximab) by inappropriately excluding biosimilar competitors violates federal antitrust laws and undermines the principal goals of the federal Biologics Price Competition and Innovation Act (BPCIA).

"By offering highly similar therapeutic options for patients, doctors and health plans, biosimilars foster therapeutic choice and increased access to biologic medicines around the world," said John Young, Pfizer's group president, Essential Health. "For U.S. patients and providers to realize the benefits of biosimilars, new and existing biosimilar entrants should have a fair chance to compete with originator products – now and in the future – based on lawful pricing and access practices. By supporting the availability of biosimilar therapies, we can help ensure that patients have better access to a wide range of lower cost therapeutic options."

The U.S. biosimilars marketplace is at a relatively early stage of development compared to other countries such as those in Europe. Since Congress passed the BPCIA, which became law in 2010, three biosimilars approved by the U.S. Food and Drug Administration (FDA) have been launched. A biosimilar to J&J's Remicade, Inflectra® (infliximab-dyyb) was launched by Pfizer in the U.S. in late 2016 as the first

biosimilar monoclonal antibody (mAb).

The complaint describes how insurers originally classified Inflectra at parity with Remicade – meaning, there was no medical reason to favor Remicade over Inflectra. However, insurers reversed course after J&J threatened to withhold significant rebates unless insurers agreed to “biosimilar-exclusion” contracts that effectively block coverage for Inflectra and other infliximab biosimilars. In the absence of such coverage, providers – who depend on reimbursement from insurers – are reluctant to stock biosimilars, even to service Medicare and Medicaid patients where there is widespread coverage for Inflectra. Additionally, J&J offered providers anticompetitive contracts conditioned on the providers not purchasing biosimilars to Remicade in exchange for discounts on Remicade. These anticompetitive practices are preventing physicians from trying and patients from accessing the biosimilar.

J&J’s exclusionary contracts have also caused insurers not to cover Pfizer’s Inflectra even though the Pfizer biosimilar is available at a Wholesale Acquisition Cost (WAC) that is 19 percent lower than that of Remicade, and has an Average Selling Price (ASP) that is more than 10 percent lower – with Pfizer offering additional pricing concessions to compete vigorously against the dominance of Remicade. Moreover, the recent Q3 ASP published by the Centers for Medicare and Medicaid Services (CMS) continues the trend of increases in Remicade's ASP despite the launch of Inflectra, which has seen a decline in its ASP each quarter.

“Congress enacted the BPCIA to improve patient access to more affordable treatment options and to foster meaningful price competition for biologic products,” said Douglas Lankler, executive vice president, general counsel, Pfizer Inc. “J&J’s behavior runs counter to the spirit of this law and to U.S. antitrust laws. We are filing this suit to help ensure that patients can benefit from, and have access to, lower cost biosimilar therapies.”

A biosimilar – by definition – has no clinically meaningful differences from the original product in terms of safety, purity, and potency. J&J’s biosimilar exclusionary contracts are designed solely to prevent Inflectra from being able to compete on its primary point of differentiation – price. This behavior prevents patients from gaining access to important lower cost biosimilar therapies.

“As evident by their success in markets such as Europe, we know biosimilars can improve patient access to important, life-saving medicines. We stand with patients and are fully committed to deliver on the increased therapeutic choices and potential savings that biosimilars can bring; however, we must make sure there are no artificial barriers in the

commercial insurance market that may limit coverage and use of biosimilars," Young said. "It's not in the best interest of patients and our healthcare system if originator companies like J&J can use their dominant market position to prevent access to lower cost, effective biosimilar medicines in the U.S. Pfizer is committed to challenging practices like those implemented by J&J that block biosimilar options for patients and price competition – through the courts and by working with policymakers and regulators – so that patients have a wide range of treatment options available to them at a competitive price."

DISCLOSURE NOTICE: The information contained in this release is as of September 20, 2017. 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 INFLECTRA® (infliximab-dyyb) and a suit filed by Pfizer in the U.S. District Court for the Eastern District of Pennsylvania against J&J, including their potential benefits, 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, uncertainties regarding the outcome and impact of the suit filed against J&J uncertainties regarding the commercial success of INFLECTRA; the uncertainties inherent in research and development; intellectual property and/or litigation implications; relationship with the application sponsor; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of INFLECTRA; 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, 2016, 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 10-Q and 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.

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