

Synthetic Approaches to the New Drugs Approved During 2015

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Plus the 28 other New Drugs marketed in 2015

ABSTRACT: New drugs introduced to the market every year represent privileged structures for particular biological targets. These new chemical entities (NCEs) provide insight into molecular recognition while serving as leads for designing future new drugs. This annual review describes the most likely process-scale synthetic approaches to 29 new chemical entities (NCEs) that were approved for the first time in 2015.

1. INTRODUCTION

The most fruitful basis for the discovery of a new drug is to start with an old drug.

Sir James Whyte Black, winner of the 1988 Nobel Prize in medicine¹

inaugurated 14 years ago,² this annual review presents synthetic methods for molecular entities that were approved for the first time by governing bodies within various countries during the past year. Because drugs tend to have structural homology across similar biological targets, it is widely believed that the knowledge of new chemical entities and approaches to their construction will greatly enhance the ability to discover new drugs more efficiently. The pharmaceutical industry enjoyed a productive year during 2015, 50 new drugs consisting of new molecular entities (NMEs) and biologics were approved which spanned a variety of indications including the first treatment for female hypoactive sexual desire disorder, binge eating disorder, the first vaccine for dengue, as well as the first pharmacotherapies for three rare metabolic disorders.³ The field of oncology was the most active therapeutic area in terms of numbers of drug approvals in 2015, with 14 new drugs and biologics within this class reaching the market, including four new drugs for the treatment of multiple myeloma. Furthermore, six hematologic therapies and six metabolic treatments were brought to the market. In contrast to the productivity realized industrywide during 2014 and 2015, the number of medicines approved decreased in 2016. Nonetheless, an additional 21 new

drugs were in the process of approval from various governing bodies during 2015 but were not launched before the end of the year.⁴

This review describes the syntheses of the 29 small-molecule NCEs that were approved for the first time in 2015 around the world (Figure 1). New indications for previously launched medications, new combinations, new formulations of existing drugs, and drugs synthesized purely via bioprocesses or peptide synthesizers have been excluded from this review.

Drugs presented in this review are divided into eight therapeutic categories: anti-infective, cardiovascular, neuroscience, gastrointestinal, hematologic, metabolic, musculoskeletal, and oncology. Within the therapeutic areas, drugs are ordered alphabetically by generic name. Although the scale of the synthetic routes were not explicitly disclosed in most cases, this review presents the most likely scalable routes that have been disclosed within published or patent literature beginning from commercially available starting materials.

2. ANTI-INFECTIVE DRUGS

2.1. Isavuconazonium Sulfate (Cresemba). Isavuconazonium sulfate is a broad spectrum antifungal agent that was codiscovered by Basilea Pharmaceutica (a subsidiary of Hoffmann–La Roche acquired in 2000) and Astellas Pharma, which obtained its first approval by the United States Food and

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