Welcome to the **Fourth Annual Oncology Guide to New FDA Approvals**

The Lynx Group is pleased to bring you the *Fourth Annual Oncology Guide to New FDA Approvals*. The goal of this *Guide* is to offer oncologists, pharmacists, oncology nurses, and other healthcare stakeholders a comprehensive overview of new drugs approved by the US Food and Drug Administration (FDA) in 2018 for the treatment of different types of cancer, including hematologic and oncologic malignancies. This practical tool offers a quick, evidence-based resource for hematology/oncology professionals to guide their medication-related decision-making and help ensure the administration of recent medicines for appropriate patients.

As noted in the introduction to the Oncology Overview article (page 6), 2018 was a record year for the FDA in terms of the total number of new molecular entities (NMEs) and new biologic license applications (BLAs) approved, amounting to 59 novel drugs in all disease states, compared with the 46 total NMEs and BLAs approved in 2017 and only 22 in 2016. Of these 59 new drugs, 32% (19) were first-in-class medicines, perhaps reflecting a renewed effort to develop new types of therapies in different diseases, especially in cancer.

The Oncology Overview provides a detailed review of the new or expanded indications for the hematology/oncology drugs that were previously available on the market for other indications and have received new indications in 2018 for new types of cancer or for new populations of patients with cancer.

Overall, 2018 saw an increase in drug makers’ entrance into the biosimilar market, mostly in cancer, with 6 of the total 7 biosimilars approved in 2018 being for cancer drugs.

This *Guide* also provides a comprehensive directory to all the novel hematology/oncology NMEs and BLAs approved by the FDA in 2018 (see page 14). In addition, the directory discusses the 6 new hematology/oncology biosimilars (see page 17) approved by the FDA in 2018.

Indeed, 2018 was a strong year for developing new therapies for cancer, including several first-in-class treatments for patients who had no approved treatment before, such as a new drug for patients with Sézary syndrome or mycosis fungoides, 2 rare types of non-Hodgkin lymphoma.

As in previous years, this *Guide* includes a select sample of comprehensive drug profiles for some of the new drugs and new indications in hematology/oncology approved by the FDA in 2018. Additional comprehensive drug profiles for new cancer drugs approved in 2018 are posted online on the journal’s website.

We hope you find this publication a useful tool for incorporating up-to-date information on new pharmaceuticals within your clinical decisions and patient care.

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**EDITOR’S NOTE:** The FDA continues to make changes to the prescribing information of many drugs on an ongoing basis. The information in this *Guide* is based on each drug’s prescribing information up to January 15, 2019. The Publisher and the Editors are not responsible for any inaccuracies stemming from labeling changes, new approvals, or company updates that became available after that date. Readers are advised to review the most recent prescribing information for any future updates and revisions.