Table 2.3 (Continued) Potential U.S. Biosimilar Candidates through 2024

Brand	Generic Name	Therapeutic Category	Worldwide Annual Sales (2015) ($millions)	Patent Expiry
Yervoy	Ipilimumab	Oncology and immunomodulators	1,411	Dec 2023
Kadcyla	Ado-trastuzumab emtansine	Oncology and immunomodulators	806	Dec 2023
Benlysta	Belimumab	Oncology and immunomodulators	324	Dec 2023
Saxenda	Liraglutide (rDNA origin)	Gastrointestinal	86	Dec 2023
Elelyso	Taliglucerase alfa	Various	15	Feb 2024
Xgeva	Denosumab	Musculoskeletal	1,405	Mar 2024
Prolia	Denosumab	Musculoskeletal	1,280	Mar 2024
Aranesp	Darbepoetin alfa	Blood	1,891	May 2024
Blincyto	Blinatumomab	Oncology and immunomodulators	35	May 2024
ChondroCelect	Autologous-cultured chondrocytes	Musculoskeletal	5	Aug 2024
Kalbitor	Ecallantide	Blood	75	Sep 2024
Ilaris	Canakinumab	Oncology and immunomodulators	260	Dec 2024
Trulicity	Dulaglutide	Endocrine	189	Dec 2024

Note: rDNA: recombinant DNA.

pharmaceutical industry is ready for a major shift in its business strategy and biosimilars will play the most significant role in patient healthcare and the FDA will engage in a most significant manner with the industry.

2.3.2.1 Global mind-set

This chapter provided a vision of the current and the future landscape of biosimilar products; given the high cost of development, it will be economical for the sponsors to take a global approach to developing these products. It is likely that a developer will launch products in countries where the IP is not an issue first, and then move on to other jurisdictions. While the focus of this book is on U.S. regulatory expectations, it will be useful for the sponsors to carve out the most conservative specifications that will be globally admissible.

2.3.2.2 Immediate needs

The immediate focus of this book is to describe the concept of biosimilarity as viewed and practiced by the U.S. FDA. How this view has helped or hurt the entry of biosimilars was recently discussed and published by the author, where issues related to expediting entry of biosimilars in the