Monoclonal antibodies (MAbs) have become the standard of care in the treatment of non-Hodgkin’s lymphoma (NHL), colorectal cancer (CRC) and HER2-positive breast cancer in Brazil and Mexico. However, the patents of MabThera (Roche’s rituximab), Herceptin (Roche’s trastuzumab), Avastin (Roche’s bevacizumab), and Erbitux (Merck Serono’s cetuximab) are expiring, and biosimilars of these agents will compete with the original brands and emerging therapies in the treatment of these cancers. The public healthcare systems in Brazil and Mexico currently provide incomplete coverage for these costly biologic treatments. Biosimilars are expected to be more affordable alternatives that may enable these cost-conscious healthcare systems to provide wider coverage for targeted biologic treatment for NHL, breast cancer, and CRC.

Questions Answered in This Report:

- Unlike generics of small molecules, biosimilars cannot be identical to the original, branded biologic, in part because of their very sensitive, biologically based production. In Brazil and Mexico, will there be differentiation between the original biologic and its biosimilar in prescriptions and large-volume purchases by public tender, given that both products will share the same molecular name? Is pharmacy-level substitution of the original biologic with the biosimilar acceptable to oncologists, hematologists, and payers in Brazil and Mexico? Once a biosimilar is approved will it be granted indication extrapolation, meaning can it be prescribed for all the indications of the original MAb, even if it lacks direct clinical evidence in an indication? How will access to biosimilars be controlled, or favored, in each market?

- The public healthcare systems in Brazil and Mexico are eager to purchase biosimilars that are expected to be less costly than the original branded biologics. Will the availability of biosimilars for NHL, breast cancer, and CRC allow these healthcare systems to provide greater coverage for targeted biologic treatment for these and other cancers? How will branded biologics and emerging therapies compete with the prices of biosimilars? In the era of biosimilars, what weight will head-to-head and pharmacoeconomic outcomes play in the coverage of emerging agents versus current mainstays?

- The biosimilars under development are intravenous (IV) infusions similar to current branded MAbs for oncology, but subcutaneous (SC) versions of branded MAbs for oncology will be
released soon. Will oncologists and hematologists prefer to prescribe SC versions of branded MAbs rather than biosimilars? For which lines of treatment? Will payers be willing to pay a higher price up front for SC delivery if they believe they will save on the administration costs of infusions? What role will pharmacoeconomic outcomes play in differentiating the reimbursement of SC branded biologics versus IV biosimilars?

- The Brazilian government has invested in the domestic production of biosimilars through industry/government partnerships known as productive development partnerships (PDPs). Which strategic partnerships have been forged for the development of biosimilars of rituximab, trastuzumab, bevacizumab, and cetuximab in these markets? What market advantages will biosimilars from these PDPs enjoy? How do Brazilian oncologists and hematologists perceive biosimilars from PDPs versus imported biosimilars and original, branded biologic products? How will these perceptions impact prescribing? What impact will the PDPs have on the entrance of foreign biosimilars to Brazil?

Scope:

This Emerging Physician & Payer Forum report draws on the insights of 164 surveyed medical oncologists and seven interviewed payers in Brazil and Mexico to explore the dynamics that will affect the use and sales of biosimilars and branded biologics for NHL, breast cancer, and CRC in these markets. Interviewees were required to be influential in determining patient access to key biologics used in the treatment of NHL, breast cancer, and CRC at the institutional or regional/national level, including the current and future uptake of biosimilars (and other copy biologics), and came from the following backgrounds:

- Brazil: Pharmacy specialist with oversight of Hospital das Clínicas’ (HC) pharmaceutical assistance programs and member of the P&T committee at the HC of the University of São Paulo (USP); Member of the pharmacy and therapeutics (P&T) committee and supply center service at INCA (Instituto Nacional do Cancer) in Rio de Janeiro; Managing medical auditor of a major HMO based in São Paulo; Brazilian physician and key opinion leader (KOL) for an NGO that provides regulatory and scientific leadership about biologic medicines and biosimilars in Latin America.

- Mexico: Coordinator of clinical practice guidelines and new drug inclusions at CENETEC-Salud; Evaluator of new oncology drugs and their efficacy in patients at IMSS and member of the Mexican Oncology Society; Medical director at ISSSTE’s “20th of November” National Medical Center with oversight of the purchase of medicines and formulary inclusion at ISSSTE.

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