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DRAFT

Testimony for July 13th Meeting of the FDA Oncologic Drugs Advisory Committee (ODAC) regarding biologics license application (BLA) 761074 for MYL-14010, a proposed biosimilar to Genentech Inc.'s HERCEPTIN (trastuzumab), submitted by Mylan GmbH.

Committee Members,

I am Harry L. Gewanter, MD, a retired pediatric rheumatologist who has spent more than thirty years treating children and youth with rheumatic diseases and other chronic and disabling conditions. I am the current Chairman of the Alliance for Safe Biologic Medicines (ASBM), an organization of patients, physicians, pharmacists, researchers, manufacturers of both innovator and biosimilar medicines, and others dedicated to ensuring patient safety remains at the forefront of all biosimilars policy discussion. Our members include several cancer patient advocacy groups which represent patients with breast and gastric cancers, two of the indications for which this proposed biosimilar to trastuzumab is seeking approval.

I believe everyone here has personally experienced or witnessed the dramatic transformation biologics have made in the lives of patients and their families. Since every treatment is a unique chemical experiment between an individual patient and the medication, I've also witnessed the variability in patient response to different medications or even different lots of the same medication. These real-world individual responses to all therapies emphasize the critical need for as much clinical data and transparency as possible with all medications, but especially with biologics, both the reference molecules and biosimilars.

Biosimilars provide opportunities for increased access to more life-altering treatment options, at reduced cost to both the patient and society. While similar, by definition, these are different molecules from their reference products and, along with the size and complexity inherent to all biologics, have the potential to produce unexpected effects in patients, including unwanted and harmful immune responses. We support the FDA's history of intense and appropriate scrutiny of all medications, both at the time of application as well as throughout the medications' lifespan. It is the only way to produce the high level of confidence necessary for biosimilars to be fully accepted and utilized by patients and their physicians.

Producing that level of confidence begins with maintaining, and building on the FDA's high approval standards. Thorough evaluations start with solid analytical and clinical biosimilarity data and proceed to clinical data focused on potential adverse effects and efficacy in the most sensitive situations. Since immunogenic effects may vary significantly between indications, the immunogenicity profile of a biosimilar should be studied in the patient population with the highest risk of an immune response.

We believe the approval of a biosimilar should be decided on a case-by-case basis for each potential indication based on sufficient supporting data rather than justifying an automatic blanket extrapolation to all indications. Ultimately, the burden of proof must be on the biosimilar manufacturer to demonstrate that their product is highly similar in structure, function and in patient response to the reference product.

Clear product identification is critical after approval to ensure safety and confidence in biologic medications. We strongly support distinguishable names for all biologics, innovator and biosimilar alike. ASBM conducted a survey of U.S. biologic prescribers which showed they supported the FDA issuing distinct names by a factor of 6-to-1. (66%-11%) We were concerned when we saw the FDA deviate from its own naming guidance with the recent approval of the biologic brodalumab absent a 4-letter suffix, but are encouraged to hear that the FDA does plan to revisit its naming and assign a distinguishing suffix.

We also believe the FDA should use its role as the lead regulator in the world to work with Dr. Rafaella Balocco at the World Health Organization to advance the WHO's BQ proposal to that establishes a 4-letter suffix system internationally. The BQ proposal is critical for global pharmacovigilance, and we believe the FDA should also encourage other regulatory authorities – Health Canada and the Australian TGA for example- to do the same.

Regarding labeling, ASBM survey asked what type of data of 400 biologic prescribers considered important to include on a biosimilar label.

Nearly 80% wanted to see: analytical data [82%], clinical data [83%], was approval for an indication based on clinical data or extrapolation? [80%] They wanted the biosimilar data to be clearly distinguished from the reference product data. [79%] And they wanted to know if the product is interchangeable. [79%]

Many drug labels are out of date. Congress should give the FDA the authority to encourage drug manufacturers to keep this essential information up to date. Updating drug labels would greatly help patients — but few companies do it.

Comprehensive data collection on a biosimilar should not end with its approval. Strong post-market surveillance data improves care and limits risks. Real world data helps us better understand these medicines and promote more efficient, safer and personalized use. The FDA's leadership through post-approval pharmacovigilance will improve care and provide further confidence in these important medications.

Patient and physician trust and confidence in biosimilars is critical to their success. It must be earned, and maintained, through high approval standards, distinguishable naming, transparent labeling, strong and comprehensive pharmacovigilance, manufacturer accountability and open communication.

Thank you for your vigilance and leadership on behalf of all Americans. I appreciate the opportunity to provide our perspectives on this important issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, FACR
Chairman, The Alliance for Safe Biologic Medicines

ASBM Steering Committee Members:

Alliance for Patient Access

American Academy of Dermatology

American Autoimmune Related Diseases Association (AARDA)

Association of Clinical Research Organizations

Colon Cancer Alliance

Global Colon Cancer Association

Global Healthy Living Foundation

Health HIV

Hepatitis Foundation International

International Cancer Advocacy Network

Kidney Cancer Association

National Psoriasis Foundation

ZeroCancer