GLOBAL HEALTHY LIVING FOUNDATION

Creaky Joints
A supportive community of people living with arthritis

FDA PUBLIC MEETING STATEMENT, OPINION AND RECOMMENDATION

Arthritis Advisory Committee Public Meeting

The committee will discuss biologics license application (BLA) 125544, for CT-P13, a proposed biosimilar to Janssen Biotech Inc.'s REMICADE (infliximab), submitted by Celltrion, Inc.

Speaker:
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Disclosure:
I have no disclosures to make regarding my travel here today.

On behalf of the non-profit Global Healthy Living Foundation and its arthritis organization, CreakyJoints, I want to thank the FDA for its commitment to listening to a diverse set of stakeholders.

We are not scientists or doctors. We are **patients**.

My name is Seth Ginsberg, co-founder of CreakyJoints and the Global Healthy Living Foundation. I was diagnosed with Spondyloarthritis at 13.

For us patients, biosimilars represent hope as well as fear. We hope for expanded treatment options through a broader formulary; we fear being switched from a drug that works to one we don't know, without participating in the promised cost reductions.

Our community is carefully processing these two emotions because biologics transform lives. Whether it's Mariah from Colorado who was able to finish her masters and law degrees or Cindi from Texas who took one last road trip with her elderly father before he died.

In addition, our community fears biosimilars could represent losing the biologic treatment we've searched years to find and worked tirelessly to gain access to. In the case of Brenda from North Dakota - a decade. A biosimilar may be essentially equivalent to a scientist, but not to the biologic patient whose life has been transformed.

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Nevertheless, at CreakyJoints we are optimistic about biosimilars and we look forward to seeing them in our therapeutic space where, through ArthritisPower, our PCORI-sponsored Patient

Powered Research Network, we will vigilantly track patient-reported outcomes. FDA is working to include patients in the regulatory process. PCORI represents a natural extension of the patient voice with PCORnet, which is a national resource for real world evidence collection.

In order to achieve the promise originally intended by the BPCIA in 2010, we are addressing patient and physician *confidence*. We believe the FDA and biosimilar manufacturers can support this effort by closely examining their supply chain and support services to ensure continuity of support and product, creating unique naming and clear labeling to allay fears, as well as a finalized interchangeability rule that eliminates payer-level switching. We also think the FDA needs to allow extrapolation, unless the mechanism of action for the extrapolated indication is not clearly understood or the drug is considered scientifically or therapeutically outdated. Patients are OK with extrapolation as long as you're extrapolating the best in class therapy. We want biosimilars to be an improvement of what we have, not the lowest common denominator of what we know. Other countries such as Canada held back full extrapolation by not including IBD.

Science is only part of biosimilar success. Use and satisfaction is where success also will be measured.

We think the approval process is the place to discuss these issues. Once approved, I and organizations like CreakyJoints will not have this platform to speak directly to regulators in a public format, as well as the drug companies in attendance.

We thank the FDA for emphasizing the value of the patient perspective through public meetings, and we continue to mobilize our patient community to create a better life for those who will benefit from biosimilars.

We welcome input and collaboration.