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This Week's Top Global Headlines

U.S.A

- **FDA approves Tecvayli under Commissioner's National Priority Voucher pilot:** The U.S. FDA has approved teclistamab (Tecvayli) in combination with daratumumab hyaluronidase-fihj for adults with relapsed or refractory multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor and an immunomodulatory agent. The approval also converts teclistamab's accelerated approval as monotherapy into traditional approval for later-line use in adults with relapsed or refractory multiple myeloma. The application was reviewed under the FDA Commissioner's National Priority Review Voucher (CNPV) pilot, which is intended to accelerate review of products that may address key national priorities. **More info here.**

EU

- **CHMP recommends 12 medicines including first combined COVID-19/influenza mRNA vaccine:** At its February 2026 meeting, the EMA's Committee for Medicinal Products for Human Use (CHMP) issued 12 positive opinions, including mCombriax, the first combined mRNA vaccine designed to protect adults aged 50 years and older against both COVID-19 and seasonal influenza. The meeting also included two negative opinions, recommendations for six biosimilar medicines, several indication extensions, and the withdrawal of an application for the bladder cancer therapy sasanlimab. **More info here.**

- **CHMP recommends Dupixent indication extension for pediatric chronic spontaneous urticaria:** The EMA's CHMP adopted a positive opinion recommending the approval of Dupixent (dupilumab) in the EU for the treatment of chronic spontaneous urticaria (CSU). This recommendation covers children aged 2 to 11 years with moderate-to-severe CSU, an inadequate response to H-1 antihistamines (H1AH), and who are naïve to anti-immunoglobulin E (IgE) therapy for CSU. A final decision is expected in the coming months, potentially making it the first biologic treatment for this pediatric population. **More info here.**

APAC

- **Japan strengthens clinical trial access through One-Stop Window and PMDA collaboration:** Japan's Ministry of Health, Labour and Welfare (MHLW) has introduced a new framework to attract international clinical trials by coordinating the International Joint Clinical Trial One-Stop Consultation Window with the Pharmaceuticals and Medical Devices Agency (PMDA). The initiative provides priority handling of PMDA consultations for high-medical-need products and allows English-language submissions for eligible emerging biopharma sponsors without a Japanese subsidiary, aiming to reduce drug lag and lower entry barriers for global developers. **More info here.**

Deep Dive: Expanding Impact After First Approval

A notable pattern is emerging across the life sciences landscape: some of the most meaningful advances are being occurring after launch, as therapies move into broader clinical settings, new patient populations, and more practical delivery models. This week's developments offer a useful snapshot of that shift and why it matters from a clinical and patient-access perspective.

The FDA's March 5 approval of **teclistamab (Tecvayli)** in combination with daratumumab hyaluronidase-fihj for relapsed or refractory multiple myeloma is a strong example. Teclistamab was first granted accelerated approval in 2022 as a later-line option for adults who had already received at least four prior lines of therapy. FDA has now approved it in an earlier treatment setting, for adults who have received at least one prior line including a proteasome inhibitor and an immunomodulatory agent. Teclistamab is a BCMA-directed CD3 T-cell engager, and this latest decision broadens how it may be used in practice. Clinically, that matters because earlier use can expand access to advanced therapies before disease progression further narrows treatment options.

A similar access story can be seen in Europe. At its February 2026 meeting, CHMP adopted a positive opinion recommending **Dupixent (dupilumab)** for children aged 2 to 11 years with moderate-to-severe chronic spontaneous urticaria who remain inadequately controlled on H1 antihistamines and are naïve to anti-IgE therapy for CSU. Dupilumab is already established across multiple immune-mediated conditions, with EMA materials listing approved uses that include atopic dermatitis, asthma, and eosinophilic esophagitis. The pediatric CSU recommendation is therefore not simply another label update; it reflects a continued widening of access to targeted biologic treatment in populations that have historically had more limited advanced treatment options.

The CHMP recommendation for **mCombriax** points to a different type of post-approval value creation: improving how preventive therapies are delivered. EMA described mCombriax as the first combined COVID-19 and influenza mRNA vaccine for adults aged 50 years and older. That matters because both respiratory infections continue to carry a substantial burden in Europe and globally. EMA's own announcement cites WHO data showing more than 281 million COVID-19 cases reported in Europe as of February 1, 2026, while ECDC materials note that seasonal influenza causes up to 50 million symptomatic cases annually in the EU/EEA. A combined vaccine approach will not solve uptake on its own, but it does align with the broader public health logic that fewer separate injections and more streamlined vaccination pathways can improve convenience and support access.

Taken together, these examples illustrate an increasingly important reality for the clinical landscape: the value of innovation is defined by the first approval and shaped by what happens next i.e., whether a therapy moves earlier in care, reaches new age groups, or becomes easier to deliver in routine practice. From a patient-access perspective, those shifts can be just as meaningful as the original approval itself.

Why This Matters

For clinical and regulatory teams, the real value of innovation is not limited to a first approval milestone. It increasingly depends on how effectively a therapy can be expanded into earlier lines of care, broader patient populations, and more practical real-world use. That is where clinical impact often deepens and where patient access can improve most meaningfully. For industry, this reinforces the importance of thinking beyond approval toward lifecycle evidence generation, indication expansion, and implementation strategy. For patients, it means that progress is not only about entirely new medicines reaching the market, but also about existing therapies becoming available sooner, to more people, and in ways that better fit routine care.

ECNE Insight: Designing Evidence for Expansion

These developments highlight a reality that clinical and regulatory teams encounter: approval is not the end point of evidence generation, but the beginning of a much broader lifecycle strategy.

As therapies expand into earlier lines of care, new patient populations, and additional indications, the evidence requirements also evolve. Regulators, clinicians, and payers increasingly expect continued clinical data generation, real-world evidence, and ongoing literature surveillance to support these expansions and maintain confidence in the product over time.

For companies, this means that evidence planning must extend well beyond the initial regulatory submission. Post-approval clinical studies, systematic evidence synthesis, safety monitoring, and ongoing scientific communication all play a critical role in ensuring that therapies can successfully move into new clinical settings and reach the patients who may benefit most.

In practice, the most successful development programs are those that treat evidence generation as a continuous process; one that connects early clinical strategy, regulatory approval, and long-term clinical adoption.

On Our Radar

- **EU | 9–12 March 2026 — EMA Clinical Trials Information System (CTIS) Sponsor Training Program:** The European Medicines Agency will host a multi-day training program for sponsors and clinical trial stakeholders focused on the **Clinical Trials Information System (CTIS)**. Sessions will cover practical aspects of trial submission, regulatory processes under the EU Clinical Trials Regulation, and operational use of CTIS for managing clinical trial applications across EU Member States. **More info here.**
- **USA | 12 March 2026 — FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting:** The U.S. FDA's Vaccines and Related Biological Products Advisory Committee will convene to discuss and make recommendations on the influenza virus strain composition for vaccines intended for the 2026–2027 influenza season. These annual meetings play an important role in shaping seasonal vaccine strategy and informing manufacturers' formulation decisions ahead of the upcoming influenza cycle. **More info here.**
- **APAC (Singapore) | 9–13 March 2026 — 29th IMDRF Management Committee Meeting:** The International Medical Device Regulators Forum (IMDRF) will convene in Singapore to discuss international harmonization priorities for medical device regulation, including exchanging insights on the latest advancements in medical device regulation and technology as well as on the strategic initiatives of the IMDRF. **More info here.**

The Friday Brief is curated by Elizabeth Weathers, PhD, RN, RGN, FAAN, Founder & CEO of ECNE Research. Follow ECNE Research on LinkedIn for ongoing insights in regulatory strategy, clinical evidence, and market intelligence.