Unlocking New Potential *for Existing Medicines*

In the biopharmaceutical industry, much attention is paid to the discovery, testing, and evaluation of novel medicines.

This attention is rightfully earned; however, another valuable path to bring medicines to patients is post-approval research—the continued investigation of therapies already making an impact on patients' lives.

Sanofi's commitment to post-approval research over several decades has resulted in new indications and expanded access for patients across numerous disease areas. While less heralded than the discovery and launch of new medicines, investigating an approved medicine's potential in additional disease states and applications can help unlock its full *economic and societal value*—allowing more people to benefit from treatments that may improve their conditions.

Why Post-Approval Research Matters: *Continuing Research After Approval Delivers Critical Benefits*

Faster Access to Treatments

Medicines with proven safety profiles can reach eligible patients years faster **than waiting for entirely new therapies to be discovered, tested, and approved.**

Optimized Care & Cost Savings

Post-approval research refines treatment strategies—**helping clinicians identify the most effective dosing, sequencing, and use patterns for specific patient groups.**

These insights can improve adherence, support better disease control, and lower reliance on multiple therapies for a single patient.

Connecting Dots Through Immunoscience

Our immunoscience R&D approach investigates the underlying causes of inflammation, **leveraging our deep understanding of biological pathways.**

This often reveals how seemingly unrelated conditions share common mechanisms, broadening the populations of patients that can benefit, particularly those with immune system disorders.

Our 2025 Milestones *for Existing Medicines*

These 2025 approvals were built on decades of post-approval research that have expanded the indications for four of our existing medicines, broadening their FDA-authorized labels to treat diverse patient populations with unmet needs.

March 2025

Flublok® (Influenza Vaccine) indication was expanded to include individuals 9-17 years old, extending the vaccine's use beyond those aged 18 and above. Flublok is now approved for use in individuals 9 years of age and older to prevent disease caused by influenza A and B strains.

April 2025

Dupixent® (dupilumab) was *approved* for the treatment of adults and adolescents aged 12 years and older with chronic spontaneous urticaria (CSU), who remain symptomatic despite histamine-1 (H1) antihistamine treatment. Dupixent is the first new targeted therapy for CSU in more than a decade.

May 2025

MenQuadfi's (meningococcal (groups A, C, Y, W) conjugate vaccine) indication was *expanded* to include children aged 6 weeks to 23 months. As infants continue to face the highest incidence of invasive meningococcal disease, this expanded indication provides a valuable public health option for parents and infants.

June 2025

Dupixent® (dupilumab) was *approved* for the treatment of adult patients with bullous pemphigoid (BP). Dupixent is the only targeted medicine approved to treat patients with BP, a chronic, debilitating, and relapsing rare skin disease affecting approximately 27,000 adults in the U.S. whose disease is uncontrolled by systemic corticosteroids.

December 2025

Cablivi® (caplacizumab-yhdp) was approved for the treatment of pediatric patients 12 years and older with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy. aTTP is an extremely rare, life-threatening disorder that affects about 1 in 10 million children each year, causing blood clots to form in small blood vessels.

Each subsequent indication or label is not merely a regulatory milestone, but the translation of innovative science into better health outcomes, fewer hospitalizations, and improved quality of life for patients around the world.

Case Study: *The Transformative Impact of Dupixent*

The regulatory journey of medicines like Dupixent, our leading biologic medicine jointly developed with Regeneron under a global collaboration agreement, demonstrates how a single scientific breakthrough can multiply its impact by expanding to new patient populations, addressing previously unmet needs, and setting new standards of care.

For many, Dupixent has provided relief where other therapies failed, improving quality of life and reducing hospitalizations.

- FDA-approved in *9 indications,* driven in part by underlying type 2 inflammation
- Secured regulatory approvals in *more than 60 countries* in one or more indications
- Treating *more than 1.4 million patients* globally

> *"Each new Dupixent indication represents years of rigorous research that expands treatment options for patients across a spectrum of diseases with underlying type 2 inflammation. This exemplifies how sustained investment in existing medicines delivers extraordinary value.*
>
> **Deborah Glasser**
> *Head, Specialty Care, North America, and U.S. Country Lead, Sanofi*

Policy That Recognizes *the Value of Innovation*

Post-approval research is an "unsung hero" of pharmaceutical science, demonstrating how an innovative ecosystem that encourages continued research can expand a medicine's value to patients and society. Unfortunately, this ecosystem is **increasingly at risk—in the U.S. and abroad—due to policy changes that undermine manufacturers' ability to invest in continued innovation.**

Post-approval research requires substantial investment—including rigorous clinical trials—to support additional indications across diverse patient populations. These investments depend on a stable and predictable policy environment that recognizes the long-term value of multi-indication medicines.

We must address the critical and urgent need for advanced economies to recognize the value of innovation in all its forms and invest boldly in the future. Without sustained investment in post-approval research, fewer new treatment options will emerge, potentially driving higher medical costs and increased hospitalizations for patients, while increasing the burden of caregivers.

Sanofi supports policy solutions that preserve biomedical innovation while ensuring affordable patient access to breakthrough therapies.

At Sanofi, we are resolute in our mission to partner with and encourage governments worldwide to promote an environment in which innovative medicines receive the recognition they deserve and are accessible to patients—because science and lives depend on it.