

## Seasonal influenza is an mRNA battleground

**LONDON, UK---22<sup>nd</sup> June 2022---ExpertREACT.** Around a 3<sup>rd</sup> of the vaccine pipeline is now nucleic acid. Incumbent manufacturers of seasonal influenza vaccines are building an mRNA presence to fend off potential newcomers, Pfizer and ModernaTX (now at Phase III)

In our latest review of the **Q2 2022 vaccine R&D pipeline (1)** operated by 7 major vaccine developers\* we count 59 verified ongoing programs at clinical development stages, Phases 1-3. These candidates are focused on 28 different pathogens/indications#. Since April 2022, our data show that GSK still has the largest number of individual vaccine programs at 16. The relative newcomer, **Moderna Therapeutics** remains in 2nd place with 12 individual programs, although its **COVID-19** effort encompasses several derivatives of the original mRNA-1273 vaccine (SARS-CoV-2 variant dependent). **Respiratory Syncytial Virus (RSV)** is still the most worked upon vaccine pathogen (9 programs) with already several large Phase III trials underway in both the maternal and elderly segments. GSK's maternal candidate (GRACE Phase III trial) is still on hold due to an unexpected safety signal but its elderly candidate (GSK3844766A) recently met its endpoints in the **AReSVi 006** study. New **COVID-19** vaccines, despite several being already licensed, are still under development/or awaiting registration. Since our last update both GSK (GPB510, SKYCovione™) and Sanofi (SP0253) have reported positive developments with their COVID-19 vaccine efforts.

One dynamic we spotted back in early 2022 is the contribution of the **Moderna Therapeutics** R&D pipeline. **Moderna** is now a major player (revenues \$18.5bn FY2021) and the overall large company\* vaccine pipeline is now approximately one-third nucleic acid-based (mRNA + DNA). This is an abrupt change from only 2 years ago when the dominant investigational vaccine platforms were recombinant protein, polysaccharide/protein conjugates and more traditional inactivated/vector-based approaches. If one looks at nearly 1400 industrial clinical trials initiated since 2014 less than <5% involved nucleic acids which were mainly DNA constructs in oncology-based applications. We now ask: how much of the future vaccine market will be mRNA?

**Sanofi, GSK and Pfizer (BioNTech)** build their mRNA vaccine presence with new programs announced since April 2022. But there have also been some failures—gaining an edge in nucleic acid technology is unpredictable. Our latest audit shows the traditional players are behind in terms of diversity offered by the current **Moderna Therapeutics** pipeline but mRNA seasonal influenza is a focus area for all as incumbent suppliers defend their franchises. In February 2022, GSK initiated a Phase 1 study with an mRNA-based seasonal influenza vaccine (**GSK4382276A, CVSQIV/CureVac**). The company is developing a second-generation mRNA COVID-19 vaccine also with Curevac (**CV2CoV**) but has stopped listing other SAM-based approaches previously in HSV-2 and rabies, although a rabies vaccine is listed at Curevac (CV7202). Sanofi also has an mRNA flu candidate, **SP0273** with Translate Bio (Phase 1) and Pfizer (BioNTech) with PF-07252220 (Phase 1). However, this month, **ModernaTX** lead the way in nucleic acid seasonal flu with its mRNA-1010 series starting first dosing in a new non-inferiority Phase III study (n=6,000, >18 yrs).

The **seasonal influenza** vaccine market has witnessed an influx of new platforms over recent years e.g., cell-culture and sf9, and it is clear that mRNA might be the next platform. On global volume terms, egg-based vaccines, based on decades-old technology still dominate, but mRNA is deemed enough of a threat for the established players to get involved.

\*GlaxoSmithKline, Sanofi Pasteur, Merck & Co, Pfizer, Janssen Vaccines & Prevention, Takeda Vaccines and Moderna Therapeutics #ModernaTX's core modalities only, excludes BioNTECH's oncology pipeline

(1) The **VacZine Analytics** Q2 2022 Vaccines Strategic Pipeline Review (CAT No: VAMV084A) (industry only) contains analysis of >1396 total clinical trials operated by >221 companies. More details can be found at: [https://www.vacZine-analytics.com/products-marketview/VAMV084\\_vaccines\\_pipeline\\_review.asp](https://www.vacZine-analytics.com/products-marketview/VAMV084_vaccines_pipeline_review.asp)

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