

NEWS DIGEST

- **OUR LATEST ARTICLE:** Why is the number of advanced therapy medicinal product (ATMP) withdrawals from the European market rising?
- Top 10 most anticipated drug launches of 2022
- What is the reformed early access scheme in France?
- NICE recommends new drug for people living with obesity

OUR LATEST ARTICLE: WHY IS THE NUMBER OF ADVANCED THERAPY MEDICINAL PRODUCT (ATMP) WITHDRAWALS FROM THE EUROPEAN MARKET RISING?

WHAT ARE ATMPs AND WHAT IS SPECIFIC ABOUT THEM?

Advanced therapy medicinal products (ATMPs) are medicinal products for human use that are based on living material and prepared industrially or manufactured by a method involving an industrial process. ATMPs can be classified into three main categories – gene therapies, somatic cell therapies and tissue-engineered products.

There are 16 ATMPs, which are commercially available in the EU.

Given that these therapies are typically indicated for very rare conditions, ATMPs often struggle with significant uncertainty on their clinical data due to the limited number of patients involved in their randomised controlled trials (RCTs) and lack of long-term effectiveness data.

As a result, the manufacturers of these products face strong pushback from regulators and payers when it comes to obtaining marketing authorisation and reimbursement across countries.

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TOP 10 MOST ANTICIPATED DRUG LAUNCHES OF 2022

THE NEWS

There were 55 new drug approvals at the FDA last year and biopharma and the U.S. agency are still speedily getting new therapies out to patients.

But what are the most hotly tipped—and potentially most lucrative—approvals on the horizon for 2022?

There's a super broad range here, from Alzheimer's disease and diabetes to psoriasis and lung cancer. And, according to the life sciences data crunchers at Evaluate Vantage, the top 10 most anticipated drugs are set to make a collective \$26.9 billion by the middle of the decade.

Top 10 most anticipated drug launches of 2022

- | | |
|-----------------|---------------------|
| 1. Donanemab | 2. Tirzepatide |
| 3. Gantenerumab | 4. Deucravacitinib |
| 5. Bardoxolone | 6. Tezepelumab-ekko |
| 7. Vutrisiran | 8. Mavacamten |
| 9. Cita-cel | 10. Adagrasib |

source: <https://bit.ly/34ithkR>



WHAT IS THE REFORMED EARLY ACCESS SCHEME IN FRANCE?

INTRODUCTION

The 2021 Social Security Finance Law (Loi de financement de la sécurité sociale, LFSS) made provision for overhauling the early access scheme in France.

As of 1st July 2021, two new schemes – the early access scheme (accès précoce) and the compassionate access (accès compassionnel) scheme – were introduced.

These replace the previous schemes, the temporary use authorisation (autorisation temporaire d'utilisation, ATU) scheme and the recommendation for off-label use (recommandation temporaire d'utilisation, RTU) scheme.

Early Access

The early access scheme replaces the ATU de cohorte (ATUc, temporary use authorisation for a group of patients), the ATU EIT (temporary use authorisation for indication extensions of drugs which have marketing authorisation in a different indication), the post-ATU scheme (drugs for which an ATU is requested after marketing authorisation has been granted but before reimbursement listing) and the post-MA direct access schemes.

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NICE RECOMMENDS NEW DRUG FOR PEOPLE LIVING WITH OBESITY

THE NEWS

Today, 8th February, NICE has recommended a new treatment option for those living with obesity. Thousands of people living with obesity are set to benefit from a new drug which has helped those using it to reduce their weight by more than 10 per cent.

Semaglutide will be made available to adults with at least one weight-related condition and a body mass index (BMI) of at least 35 kg/m².

Semaglutide can only be prescribed as part of a specialist weight management service with multidisciplinary input (such as a tier 3 weight management programme or tier 4 specialist obesity services including surgery service) and for a maximum of two years.

Clinical trial evidence shows that people lose more weight with semaglutide alongside supervised weight loss coaching than with the support alone.

The 2019 Health Survey for England estimated 28% of adults in England were obese and a further 36% were overweight. Government estimates indicate that the current costs of obesity in the UK are £6.1 billion to the NHS and £27 billion to wider society.



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Paul Craddy
Managing Director & Founder



Graham Foxon
Managing Director & Founder

