NEWS DIGEST

- What is the price of a child's life? The affordability of rare disease therapies
- Correlating value with price in the US oncology market: Key learnings for manufacturers
- Europe: IPCEI on health to promote development of gene and cell therapies
- France: HAS extends early access authorisation to additional patients

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WHAT IS THE PRICE OF A CHILD'S LIFE? THE AFFORDABILITY OF RARE DISEASE THERAPIES

THE FACTS

Seven out of ten rare diseases have childhood onset

Only 5% of these rare diseases have a cure

30% of affected children will not make it to their fifth birthday

On top of this, although each disease is rare, it is not uncommon to have a rare disease. Therefore, there is a significant overall burden of rare diseases on health systems. For this burden to be reduced it is imperative that new therapies are developed.

But with very small patient numbers to target, and a rise in the number of orphan drugs coming to market, how can a price be decided which is sustainable for both the manufacturer and the payer?

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CORRELATING VALUE WITH PRICE IN THE US ONCOLOGY MARKET: KEY LEARNINGS FOR MANUFACTURERS

Despite the impact of the COVID-19 pandemic with many resources steered towards management of the virus, pharmaceutical expenditure in oncology treatments for the US is predicted to continue its double-digit growth, estimated to be by 12% in the next two years.

The rush of innovative oncology treatments, accompanied by the expected continued rising costs of oncology drugs, provides a public health challenge to patients and health systems in the US.

An affordable and sustainable market access landscape is key to ensure patient access to life-saving therapeutics. Consequently, companies must be equipped with a robust pricing and market access strategy that meets the requirements of the evolving oncology market and considers patient value alongside affordability.

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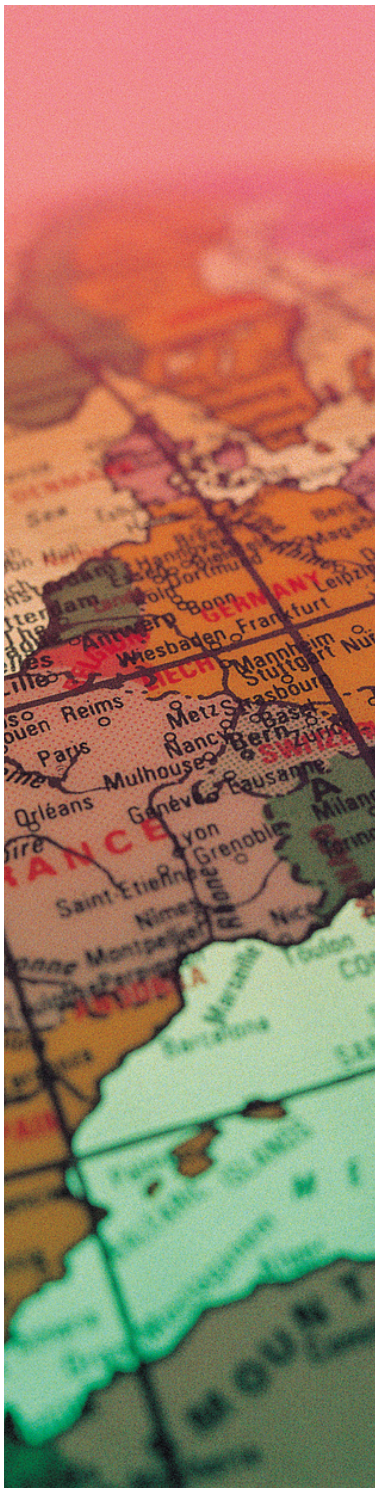
EUROPE: IPCEI ON HEALTH TO PROMOTE DEVELOPMENT OF GENE AND CELL THERAPIES

THE NEWS

A manifesto for an Important Project of Common European Interest (IPCEI) on health was signed in March 2022 between 16 EU member states which aims to develop gene and cell therapies, and treatments for rare diseases (among others).

The IPCEI was signed to address the need to equip Europe with a strong, innovative and export-friendly healthcare industry that is able to meet the challenges posed by the future of medical care, and to share a strategic vision for developing lasting and innovative European manufacturing capabilities with regards to critical products, notably pharmaceuticals.



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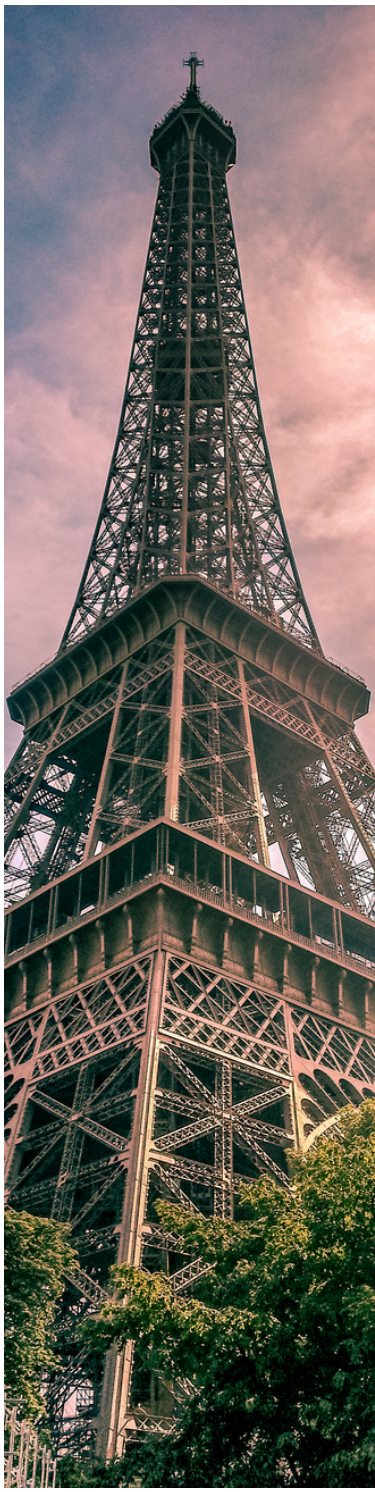
FRANCE: HAS EXTENDS EARLY ACCESS AUTHORISATION TO ADDITIONAL PATIENTS

THE NEWS



The High Authority for Health (Haute Autorité de Santé, HAS) has extended the early access (accès précoce) authorisation (click here for more on the early access scheme) granted to Evusheld (tixagevimab/cilgavimab) in December 2021 as a preventative treatment for COVID-19 to cover additional patients.

In a 7th March 2022 opinion the HAS notes that the drug's "safety and efficacy are strongly presumed for all immunocompromised patients who also demonstrate a weak, or no, response to vaccination".

Consequently, the early access authorisation is extended to cover adolescents aged 12 years and over and weighing more than 40kg under the same conditions as the adult population (ie who demonstrate a weak or no response to vaccination and who belong to one of the sub-groups at very risk of a severe form of COVID-19, and to those not eligible for vaccination and at high risk of a severe form of COVID-19).

The authorisation was previously limited to patients aged 18 years and over fulfilling these criteria.

Source > https://ansm.sante.fr

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"We always welcome your thoughts and opinions on the topics raised here.

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Paul Craddy
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