NEWS DIGEST

- What are patient-reported outcomes and why are they important?
- Continuing the push for innovation: Key learnings following China's most recent NRDL update
- UK: Lumykras first drug to come through ILAP and receive positive recommendation from NICE
- Spain: 92% of CAR-T therapy requests approved for leukaemia patients

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WHAT ARE PATIENT-REPORTED OUTCOMES AND WHY ARE THEY IMPORTANT?

SETTING THE SCENE...

The assessment of the level of benefit through the measurement of treatment outcomes is the cornerstone of clinical trials. Traditionally, these measurements were physical recordings taken by a medical professional or clinical trial staff.

However, over the last 10-20 years, patient-reported outcomes (PROs) have become commonplace. With the acceleration of digitisation introduced by the COVID pandemic, digital PROs are now increasingly utilised within trials.

Our latest educational blog will explore what PROs are, explains why they of growing importance in the digital age and how they are perceived by health technology assessment (HTA) agencies.

Keep reading > https://bit.ly/3C0WSM9

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CONTINUING THE PUSH FOR INNOVATION: KEY LEARNINGS FOLLOWING CHINA'S MOST RECENT NRDL UPDATE

THE UPDATE

In December 2021, China once again updated its National Reimbursed Drugs List (NRDL) and in line with industry expectations, expanded further to include more innovative and rare disease products.

Now that the updates have been implemented, and the dust has settled, it's time for manufacturers to take stock of the recent changes and begin considering what this means for China from a market access perspective.

Building on Simon-Kucher's recent analysis, we outline the key updates to the 2021 NRDL and discuss what this is showing about the Chinese market.

Source: https://bit.ly/3v9IkIu

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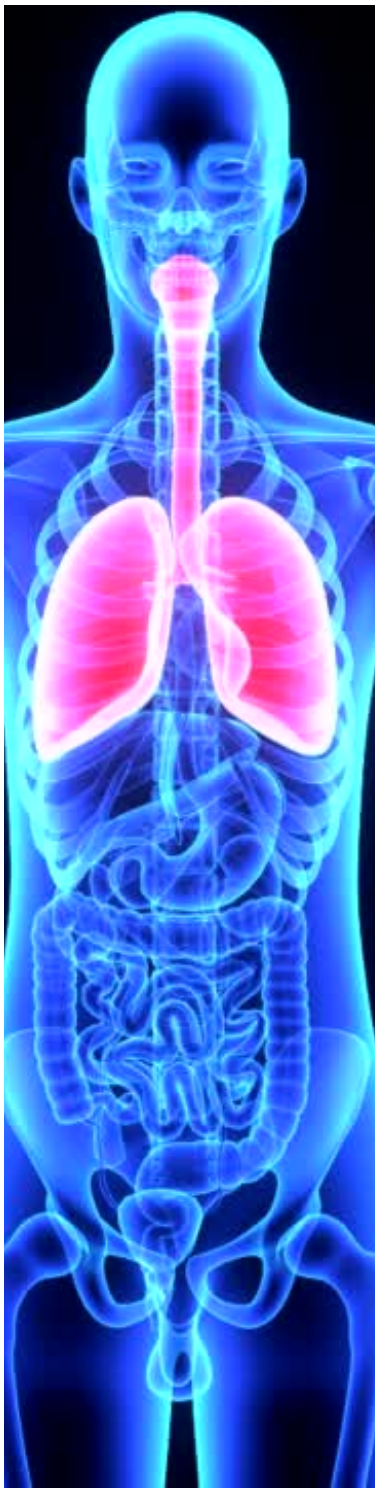
LUMYKRAS FIRST DRUG TO COME THROUGH ILAP AND RECEIVE POSITIVE RECOMMENDATION FROM NICE

THE NEWS



Amgen's Lumykras (sotorasib) has become the first active new technology to come through the Innovative Licensing and Access Pathway (ILAP – launched in January 2021 with the aim of delivering safe, early patient access to medicines by providing a mechanism for key regulatory bodies in the UK to work together and support the companies developing them) and receive a positive recommendation from the National Institute for Health and Care Excellence (NICE).

According to NICE, Lumykras is approved for use in the Cancer Drugs Fund (CDF) to enable "further direct comparative data, long-term evidence and information around cost effectiveness" to be collected and reassessed by the Institute in the future to determine whether it should be recommended for routine use in the national health service (NHS).

The therapy, a once-a-day tablet, is approved for the treatment of patients with the KRAS G12C gene mutation of non-small-cell lung cancer who have progressed on, or are intolerant to, platinum-based chemotherapy and/or immunotherapy.

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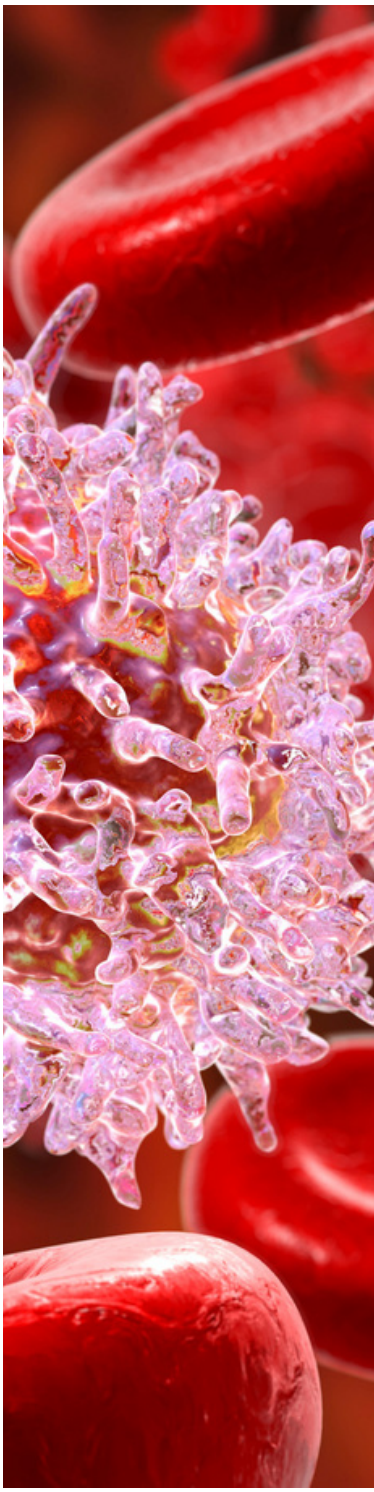
SPAIN: 92% OF CAR-T THERAPY REQUESTS APPROVED FOR LEUKAEMIA PATIENTS

THE NEWS



According to the Minister for Health, Carolina Darias – thanks to the Strategic Plan for Advanced Therapies (Plan Estratégico de Terapias Avanzadas) – a total of 687 requests, from 17 autonomous communities, have been received for the treatment of patients with CAR-T therapies.

Of these, 92% were approved in the case of patients with leukaemia.

To continue to improve access to these drugs, the Minister confirmed that the government is working to identify new centres able to administer CAR-T therapies.

Darias also stated that the government is working to increase the availability of alternative medicines within the national health service.

For example, Vyxeos liposomal (daunorubicin/cytarabine) has just been approved for reimbursement for the treatment of acute myeloid leukaemia, noted Darias.

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Paul Craddy
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Graham Foxon
Managing Director & Founder

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