

## Market Round-up

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### General Market News:

- Japan's **Takeda** family brands **Shire** deal 'a disaster'  
[LINK](#)
- **GSK** says U.S. FDA wants more information on its pulmonary drug **Nucala**.  
[LINK](#)
- **AstraZeneca / Amgen's** first-in-class asthma drug **tezepelumab** gets breakthrough status  
[LINK](#)
- **Shire** has bought **sanaplasma**, a plasma collection company headquartered in Switzerland  
[LINK](#)
- **Mylan** strikes \$463 million deal with **Novartis** for CF product line.  
[LINK](#)
- In **Novartis'** latest restructuring move for 2018, they have announced plans to sell **US generic oral solids** and **dermatology** businesses to **Aurobindo Pharma US**.  
[LINK](#)
- **Takeda** considering sale of **Shire** eye care business once acquisition completes.  
[LINK](#)
- **MSD** to file antibiotic **Zerbaxa** for pneumonia.  
[LINK](#)
- **Novartis** real-world evidence confirms efficacy and safety benefits of **Cosentyx®** in daily life for psoriasis patients. (*press release*)  
[LINK](#)
- **Pfizer, Merck** combination therapy shows significant improvement in Phase III.  
[LINK](#)
- **Novartis's** breakthrough cancer drug **Kymriah** has been approved in Europe. Now the battle over price has commenced.  
[LINK](#)
- **MSD** share positive results in antibiotic trial for **ZERBAXA®**.  
[LINK](#)
- **Merck, Pfizer's** immuno-drug **Bavencio** has been shown to alleviate kidney cancer in trials.  
[LINK](#)

## **Biosimilars:**

- The clinical director of the NCPE - **Professor Michael Barry**, has called on the HSE to increase the uptake on biosimilar medicines.  
[LINK](#)
- FDA grants priority review to **Merck's** application for new **Keytruda** indication.  
[LINK](#)

## **NCPE Drug Updates**

- A full pharmacoeconomic assessment has been recommended in respect of **Pfizer's Inotuzumab ozogamicin (Besponsa®)**
- A full pharmacoeconomic assessment has been recommended in respect of **Bristol-Meyers Squibb's Nivolumab (Opdivo®)**
- A full pharmacoeconomic assessment has been recommended in respect of **Otsuka Pharmaceutical's Tolvaptan (Jinarc®)**

## **Drug Approvals:**

- EU regulators have approved **Shire's Veyvondi** for the bleeding disorder von Willebrand Disease. The treatment was approved by the FDA under the brand name **Vonvendi** in 2015.  
[LINK](#)
- EU regulators have granted approval for a label expansion of **MSD's Keytruda** for use in combination with chemotherapies  
[LINK](#)
- **Astellas** obtains regulatory approval for global Phase III trial of **zolbetuximab** for gastric cancer treatment.
- **AstraZeneca** and **Amgen** have received breakthrough therapy designation for **tezepelumab** to treat severe asthma.  
[LINK](#)

## **Brexit:**

- Drug companies stockpile pharmaceuticals ahead of Brexit.  
[LINK](#)
- The UK government publishes more no-deal Brexit advice papers.  
[LINK](#)
- Ireland can be hub for dispute resolution after Brexit, says judge.  
[LINK](#)

## **Further Reading:**

- Five drugs manufactured in Ireland for the treatment of cancer and heart disease are not sanctioned for use here, even though they are exported from Ireland for use in other European countries.  
[LINK](#)
- **Novartis** survey shows psoriasis patients want treatment effect beyond clear skin.  
[LINK](#)

- Major pharmaceutical companies in the US including Novartis Pfizer and Merck have announced facility closures and the relocation of drug products, as Hurricane Florence approaches southeastern shores.  
[LINK](#)
- **Novartis** announces NEJM publication of landmark **PARADIGMS** study demonstrating significant benefit of **Gilenya®** in children and adolescents with relapsing multiple sclerosis  
[LINK](#)
- India bans 328 combination drugs in setback for pharmaceutical companies  
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