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Highlights from the week of
22nd June - 29th June

## Gilead Sciences

*( FDA, EU, Approval )*

FDA and EC grant approval to Gilead's TRODELVY for the treatment of adults with unresectable, locally advanced, mTNBC

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## Merck

*( FDA, Approval )*

FDA approves Merck's KEYTRUDA and KEYTRUDA QLEX, each in combination with TRODELVY, for the first-line treatment of adults with unresectable, locally advanced, or metastatic TNBC

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## AbbVie

*( EU, Approval )*

AbbVie's MAVIRET obtains EC approval to treat acute HCV infection in those aged 3 years and older

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## AstraZeneca

*( EU, Approval )*

EC provides approval to AstraZeneca and Daiichi Sankyo's ENHERTU as monotherapy to treat adults with unresectable or metastatic HER2-positive IHC3+ solid tumours

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**Merck** *( EU, Approval )*

EC approves Merck's KEYTRUDA in combination with PADCEV as neoadjuvant treatment and to continue as adjuvant therapy after radical cystectomy for adults with MIBC

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**Henlius** *( EU, Approval )*

Henlius gets EC approval for combining HETRONIFLY with chemotherapy to treat unresectable, locally advanced, or metastatic sqNSCLC

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**Sanofi** *( EU, Approval )*

EC approves Sanofi's CENRIFKI for the treatment of secondary progressive MS that are without relapses in the last two years

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**AbbVie** *( Health Canada, Approval )*

Allergan Aesthetics, part of AbbVie, gains Health Canada approval for BOEY, that provides temporary improvement in the appearance of moderate to severe glabellar lines in adults

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**Sanofi** *( MHLW, Approval )*

Japan's MHLW grants approval to Sanofi's WAYRILZ for the treatment of persistent or chronic ITP in those with insufficient response or tolerability problems

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**AstraZeneca** *( CHMP, Positive Opinion )*

DATROWAY, from AstraZeneca and Daiichi Sankyo, gets positive CHMP opinion as a 1st-line monotherapy to treat unresectable or metastatic TNBC

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**Eli Lilly** *( CHMP, Positive Opinion )*

CHMP issues positive opinion for Eli Lilly's JAYPIRCA to treat adults with CLL across all lines of therapy

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**Eli Lilly** *( Acquisition )*

Eli Lilly acquires Centessa Pharmaceuticals to advance treatments for narcolepsy and other sleep-wake disorders

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**STADA** *( Acquisition )*

STADA acquires Orifarm's 16 long-established VMS products, strengthening its positions in the Nordics, Belgium and Poland

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**AstraZeneca** *( Phase 3, Results )*

AstraZeneca's Phase 3 MULBERRY trial evaluating ALXN1850 demonstrates clinically meaningful improvement in children's bone health, achieving an RGI-C score of 1.67 at week 25 compared to placebo

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**Merck** *( Phase 3, Results )*

Merck's Phase 3 ATLAS-UC induction-only study evaluating tulisokibart met its primary and key secondary endpoints with no safety concerns at week 12 in moderate to severely active ulcerative colitis

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**Pfizer** *( Phase 3, Results )*

Pfizer's Phase 3 SigVie-002 study evaluating sigvotatug vedotin for adults with locally advanced, unresectable, or metastatic NSCLC demonstrated a stronger trend in OS and PFS over docetaxel