NEWS RELEASE

Genentech to Present New Key Clinical and Real-world Data at ECTRIMS-ACTRIMS 2023 Showcasing Strength of Long-term Outcomes in MS and NMOSD

10/2/2023

–– Late-breaking results from Phase III trial of Ocrevus (ocrelizumab) subcutaneous injection and Phase II trial of BTK inhibitor fenebrutinib in multiple sclerosis (MS) will be presented

–– 10-year Ocrevus efficacy and safety data show significant benefit in slowing long-term disability progression and consistent long-term safety profile in MS

–– Additional Ocrevus real-world and clinical data show impact for underrepresented populations including more than 3,200 pregnant women and Black and Hispanic/Latinx patients with MS

–– Long-term safety data and late-breaking efficacy data from Phase III trial of Enspryng (satralizumab) in neuromyelitis optica spectrum disorder (NMOSD) will be presented

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), will present new data for Ocrevus® (ocrelizumab) and investigational Bruton's tyrosine kinase (BTK) inhibitor fenebrutinib for multiple sclerosis (MS), and Enspryng® (satralizumab) for neuromyelitis optica spectrum disorder (NMOSD). In total, Genentech will be presenting 36 abstracts at the 9th Joint ECTRIMS-ACTRIMS Meeting (European and Americas Committees for Treatment and Research in Multiple Sclerosis) from October 11-13, 2023. Late-breaking data in MS includes the Phase Ib OCARINA I and Phase III OCARINA II studies, evaluating an investigational subcutaneous Ocrevus injection. In addition, the Phase II FENopta study of fenebrutinib for people living with MS, and late-breaking Enspryng data for people with NMOSD, which includes longer-term data from the Phase III SAkuraMoon study, will also be presented.

“It is gratifying to see that Ocrevus and Enspryng continue to show a favorable benefit/risk profile over many years in MS and NMOSD, and we are also pleased to share late-breaking results from our investigational MS medicine fenebrutinib and Ocrevus subcutaneous injection,” said Levi Garraway, M.D., Ph.D., Genentech’s chief medical officer and head of Global Product Development. “We’ve developed these latest innovations with the goal of further improving the day-to-day lives of those living with MS.”

Multiple sclerosis (MS)

Genentech will present 29 abstracts in MS, including three late-breaking presentations from the Phase Ib OCARINA I and Phase III OCARINA II studies on the Ocrevus subcutaneous injection in people with MS and the Phase II FENopta study of BTK inhibitor fenebrutinib in people with MS.

Highlights also include 10-year milestone data from the open-label extensions of Phase III OPERA I and II studies in relapsing MS (RMS) and ORATORIO study in primary progressive MS (PPMS) that show benefit on slowing long-term disability progression. Ocrevus is the only medicine approved for both RMS and PPMS, and by slowing disability progression it has fundamentally changed the landscape of MS treatment, with more than 300,000 patients treated globally. Safety outcomes from more than 6,000 patients across 12 Ocrevus clinical trials further support the medicine’s consistent favorable safety profile over 10 years.

Genentech safety data will report pregnancy and infant outcomes from more than 3,200 pregnancies, and separate real-world data on pregnant women in the international MSBase registry will provide insights on the impact of Ocrevus and other disease-modifying therapies on relapses during and post-pregnancy. Further, one-year data from the first-ever clinical trial in Black and Hispanic/Latinx people with MS (Phase IV CHIMES trial) will show Ocrevus effectively controlled disease activity.

Neuromyelitis optica spectrum disorder (NMOSD)

Genentech will present seven NMOSD abstracts, including late-breaking, longer-term data from the Phase III SAkuraMoon open-label extension study and real-world data evaluating Enspryng in people with NMOSD.

Infection is a major comorbidity in people with NMOSD, and analyzes comparing infection rates across clinical trials, post-marketing settings and U.S. claims data suggest overall lower rates in the Enspryng-treated population.

Follow Genentech on X via **@Genentech** and keep up to date with ECTRIMS-ACTRIMS 2023 news and updates by using the hashtag #MSMilan2023. Below are the details of all Genentech presentations.

Medicine	Abstract title	Presentation number (type) Presentation date (session) Time
Regular abstracts available from October 01, 2023 at 8:00 CEST. *Late-breaking abstracts available from October 11, 2023 at 8:00 CEST.		
Ocrevus for MS	Subcutaneous ocrelizumab in patients with multiple sclerosis: results of the Phase III OCARINA II study	P370 (poster) October 11 (Late Breaking Abstracts*, Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Subcutaneous ocrelizumab in patients with multiple sclerosis: results of the Phase Ib dose-finding OCARINA I study	P371 (poster) October 11 (Late Breaking Abstracts*, Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	The patient impact of 10 years of ocrelizumab treatment in multiple sclerosis: long-term data from the Phase III OPERA and ORATORIO studies	P302 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Safety of ocrelizumab in multiple sclerosis: updated analysis in patients with relapsing and primary progressive multiple sclerosis	P304 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Disease activity during pre-conception, pregnancy and postpartum in women with MS receiving ocrelizumab or other disease-modifying therapies in a real-world cohort	O173 (oral) October 13 (Scientific Session 20: Female health) 12:35 - 12:42 CEST
	One-year analysis of efficacy and safety in Black and Hispanic patients with relapsing multiple sclerosis receiving ocrelizumab treatment in the CHIMES trial	P691 (poster) October 12 (Poster Presentation Session 2) 5:00 - 7:00 PM CEST
	Ocrelizumab dose selection for treatment of paediatric relapsing-remitting multiple sclerosis: preliminary pharmacokinetic, safety and efficacy results from the OPERETTA 1 study	P034 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Pregnancy and infant outcomes in women receiving ocrelizumab for the treatment of multiple sclerosis: analysis of the largest available outcome database	P061 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Cerebrospinal fluid neurofilament heavy levels correlate with spinal cord lesions and disability in multiple sclerosis	P241 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Combining measures from clinical assessments, imaging and fluid biomarkers at one year to predict MS progression at two years	P258 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Composite confirmed disability worsening is a useful clinical trial endpoint for multiple sclerosis focusing on disability progression	P283 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Reduction of intrathecal immunoglobulin levels with ocrelizumab treatment in relapsing and primary progressive multiple sclerosis	P653 (poster)

		October 11 (Poster Presentation Session 2) 5:00 - 7:00 PM CEST
	Low disability accumulation after 4-year ocrelizumab therapy in treatment-naive patients with early-stage relapsing-remitting multiple sclerosis; data from the Phase IIIb ENSEMBLE study	P688 (poster) October 12 (Poster Presentation Session 2) 5:00 - 7:00 PM CEST
	Persistence to ocrelizumab compared with other disease-modifying therapies for multiple sclerosis in the German NeuroTransData registry	P732 (poster) October 12 (Poster Presentation Session 2) 5:00 - 7:00 PM CEST
	Utility and implementation of a federated research infrastructure to assess lack disease stability as a real-world surrogate of PIRA, by combining MS clinical trial and real-world cohort data (the INTONATE MS consortium)	P1181 (e-poster)
	Immunological signatures associated with ocrelizumab treatment in early relapsing-remitting multiple sclerosis (RRMS): new data on T cell function and pro/anti-inflammatory monocytes of the 12-month interim analysis from the MA30143 Phase IIIb (ENSEMBLE) substudy	P1460 (e-poster)
	Real-world safety data from up to 4.5 years of ocrelizumab in relapsing and primary progressive multiple sclerosis - a CONFIDENCE interim analysis	P333 (e-poster)
	Real-world effectiveness of ocrelizumab in patients with primary progressive multiple sclerosis grouped by EDSS at baseline – a CONFIDENCE study interim analysis	P336 (e-poster)
	Specific unmet medical needs in the care of patients with relapsing multiple sclerosis: final results from the PROFILE RMS study	P738 (e-poster)

	Disease-related knowledge and patient perceptions in relapsing-remitting multiple sclerosis	P1189 (e-poster)
	MS patients treated with ocrelizumab using BRISA - an MS specific app in Germany	P1594 (e-poster)
	Ocrelizumab safety under real-world conditions: Contrasting investigator-reported safety with patient-reported safety in people with multiple sclerosis (CONFIDENCE, COMPASS and TrotzMS)	P334 (e-poster)
	Development of a self-assessment tool for the autonomy of patients with multiple sclerosis (ms)	P1190 (e-poster)
	Implications of progression independent of relapse activity (PIRA) for multiple sclerosis clinical trials: item banks could provide the precise patient-reported outcome measures needed	P478 (e-poster)
	Unsupervised analysis reveals that memory IgA B cells are spared by ocrelizumab treatment	P762 (e-poster) October 11 (Late Breaking Abstracts*, Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Drug combination discovery for treatment of Multiple Sclerosis using machine learning	P790 (poster) October 11 (Late Breaking Abstracts*, Poster Presentation Session 1) 4:30 - 6:30 PM CEST
Fenebrutinib for MS	Cerebrospinal fluid and MRI analyses of fenebrutinib treatment in multiple sclerosis reveal brain penetration and early reduction of new lesion activity: results from the Phase II FENopta study	O187 (oral) October 13 (Scientific Session 22: Late Breaking Abstracts*) 4:03 - 4:10 PM CEST
	Fenebrutinib, a noncovalent, reversible, Bruton's tyrosine kinase inhibitor, potently blocks neuroinflammation induced by Fcγ receptor activation in human microglial systems: implications for multiple sclerosis treatment	P686 (poster) October 12 (Poster Presentation Session 2) 5:00 - 7:00 PM CEST
Floodlight™ in MS	Smartphone-based passive monitoring of gait in people with progressive multiple sclerosis	P100 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
Enspryng for NMOSD	Long-term efficacy of satralizumab in patients with AQP4-IgG+ NMOSD: updated analysis from the open-label SAkuraMoon study	P362 (poster) October 11 (Late Breaking Abstracts*, Poster Presentation Session 1)

		4:30 - 6:30 PM CEST
	Infection in NMOSD: an analysis of the patterns of infection in SAkuraMoon (an open-label study to evaluate the long-term safety and efficacy of satralizumab) with post-marketing data and US-based health claims data	P301 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Clarification of blood-retinal barrier on AQP4-peptide immunized mice	P115 (poster) October 11 (Poster Presentation Session 1) 4:30 - 6:30 PM CEST
	Addressing the burdens of neuromyelitis optica spectrum disorder amid challenges of the COVID-19 pandemic: real-world perspectives from patients	P1014 (e-poster)
	Satralizumab treatment in adults with AQP4-IgG-seropositive neuromyelitis optica spectrum disorder: a retrospective case series	P1036 (e-poster)
	Relapse under the prescription of satralizumab in neuromyelitis optica spectrum disorder: analysis of a Japanese claims database	P1557 (e-poster)
	Use of immunosuppressive therapy among patients with NMOSD using satralizumab treatment: a study based on Japanese real-world data	P1574 (e-poster)

About multiple sclerosis

Multiple sclerosis (MS) is a chronic disease that affects more than 2.8 million people worldwide. MS occurs when the immune system abnormally attacks the insulation and support around nerve cells (myelin sheath) in the central nervous system (brain, spinal cord and optic nerves), causing inflammation and consequent damage. This damage can cause a wide range of symptoms, including muscle weakness, fatigue and difficulty seeing, and may eventually lead to disability. Most people with MS experience their first symptom between 20 and 40 years of age, making the disease the leading cause of non-traumatic disability in younger adults.

People with all forms of MS experience disease progression – permanent loss of nerve cells in the central nervous system – from the beginning of their disease even if their clinical symptoms aren't apparent or don't appear to be getting worse. Delays in diagnosis and treatment can negatively impact people with MS, in terms of their physical and mental health, and contribute to the negative financial impact on the individual and society. An important goal of treating MS is to slow, stop and ideally prevent disease activity and progression as early as possible.

Relapsing-remitting MS (RRMS) is the most common form of the disease and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. Approximately 85% of people with MS are initially diagnosed with RRMS. The majority of people who are diagnosed with RRMS will eventually transition to secondary progressive MS (SPMS), in which they experience steadily worsening disability over time. Relapsing forms of MS (RMS) include people with RRMS and people with SPMS who continue to experience relapses. Primary progressive MS (PPMS) is a debilitating form of the disease marked by steadily worsening symptoms but typically without distinct relapses or periods of remission. Approximately 15% of people with MS are diagnosed with the primary progressive form of the disease. Until the FDA approval of Ocrevus, there had been no FDA-approved treatments for PPMS.

About Ocrevus

Ocrevus is the first and only therapy approved for both relapsing forms of MS (RMS) (including relapsing-remitting MS [RRMS] and active, or relapsing secondary progressive MS [SPMS]), in addition to clinically isolated syndrome [CIS] in the U.S.) and primary progressive MS (PPMS). Ocrevus is a humanized monoclonal antibody designed to target CD20-positive B cells, a specific type of immune cell thought to be a key contributor to myelin (nerve cell insulation and support) and axonal (nerve cell) damage. This nerve cell damage can lead to disability in people with MS. Based on preclinical studies, Ocrevus binds to CD20 cell surface proteins expressed on certain B cells, but not on stem cells or plasma cells, suggesting that important functions of the immune system may be preserved. Ocrevus is administered by intravenous infusion every six months. The initial dose is given as two 300 mg infusions given two weeks apart. Subsequent doses are given as single 600 mg infusions.

About fenebrutinib

Fenebrutinib is an investigational oral, reversible and non-covalent Bruton's tyrosine kinase (BTK) inhibitor that blocks the function of BTK. BTK, also known as tyrosine-protein kinase BTK, is an enzyme that regulates B-cell development and activation and is also involved in the activation of innate immune system myeloid lineage cells, such as macrophages and microglia. Pre-clinical data have shown fenebrutinib to be potent and highly selective, and it is the only reversible inhibitor currently in Phase III trials for MS. Fenebrutinib has been shown to be 130 times more selective for BTK vs. other kinases. These design features may be important as the high selectivity and reversibility can potentially reduce off-target effects of a molecule.

Fenebrutinib is a dual inhibitor of both B-cell and microglia activation. This dual inhibition may be able to reduce both MS disease activity and progression, thereby potentially addressing the key unmet medical need in people living with MS. The Phase III program includes two identical trials in RMS (FENhance 1 & 2) with an active teriflunomide comparator and one trial in primary progressive MS (PPMS) (FENtrepid) in which fenebrutinib is being evaluated against Ocrevus® (ocrelizumab). To date, more than 2,500 patients and healthy volunteers have been treated with fenebrutinib in Phase I, II and III clinical programs across multiple diseases, including MS and other autoimmune disorders.

About Enspryng (satralizumab)

Enspryng, which was designed by Chugai, a member of the Roche Group, is a humanized monoclonal antibody that targets interleukin-6 (IL-6) receptor activity. Enspryng was designed using novel recycling antibody technology which, compared to conventional technology, allows for longer duration of the antibody and subcutaneous dosing every four weeks.

Positive Phase III results for Enspryng, as both monotherapy and in combination with baseline immunosuppressive therapy, demonstrate that IL-6 inhibition is an effective therapeutic approach for neuromyelitis optica spectrum

disorder (NMOSD). Enspryng is currently approved for NMOSD in 85 countries with further applications under review with numerous regulators. Genentech continues to investigate Enspryng in other autoantibody-mediated rare neurological diseases characterized by elevated IL-6 levels, indications including generalized Myasthenia Gravis (gMG), Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD) and Autoimmune Encephalitis (AIE).

Enspryng was granted Breakthrough Therapy Designation for the treatment of NMOSD by the FDA in December 2018 and designated as an orphan drug for NMOSD in the United States, Europe, Russia and Japan.

In addition, the FDA has designated satralizumab as an investigational orphan drug for gMG, MOGAD and AIE (NMDAR).

About Genentech in Neuroscience

Neuroscience is a major focus of research and development at Genentech. Our goal is to pursue groundbreaking science to develop new treatments that help improve the lives of people with chronic and potentially devastating diseases.

Genentech and Roche are investigating more than a dozen medicines for neurological disorders, including MS, spinal muscular atrophy (SMA), neuromyelitis optica spectrum disorder (NMOSD), Alzheimer's, Huntington's, Parkinson's, acute ischemic stroke, Duchenne muscular dystrophy and Angelman syndrome. Together with our partners, we are committed to pushing the boundaries of scientific understanding to solve some of the most difficult challenges in neuroscience today.

About Genentech

Founded more than 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious and life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit **http://www.gene.com**.

Indications and Important Safety Information

What is Ocrevus?

Ocrevus is a prescription medicine used to treat:

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease,

and active secondary progressive disease, in adults
- Primary progressive MS, in adults.

It is not known if Ocrevus is safe or effective in children.

Who should not receive Ocrevus?

Do not receive Ocrevus if you have an active hepatitis B virus (HBV) infection.

Do not receive Ocrevus if you have had a life-threatening allergic reaction to Ocrevus. Tell your healthcare provider if you have had an allergic reaction to Ocrevus or any of its ingredients in the past.

What is the most important information I should know about Ocrevus?

Ocrevus can cause serious side effects, including:

- Infusion reactions: Infusion reactions are a common side effect of Ocrevus, which can be serious and may require you to be hospitalized. You will be monitored during your infusion and for at least 1 hour after each infusion of Ocrevus for signs and symptoms of an infusion reaction. Tell your healthcare provider or nurse if you get any of these symptoms:
    - itchy skin
    - rash
    - hives
    - tiredness
    - coughing or wheezing
    - trouble breathing
    - throat irritation or pain
    - feeling faint
    - fever
    - redness on your face (flushing)
    - nausea
    - headache
    - swelling of the throat
    - dizziness
    - shortness of breath
    - fatigue
    - fast heart beat

These infusion reactions can happen for up to 24 hours after your infusion. It is important that you call your healthcare provider right away if you get any of the signs or symptoms listed above after each infusion.

If you get infusion reactions, your healthcare provider may need to stop or slow down the rate of your infusion.

- Infection:
  - Ocrevus increases your risk of getting upper respiratory tract infections, lower respiratory tract infections, skin infections, and herpes infections. Infections are a common side effect, which can be serious. Tell your healthcare provider if you have an infection or have any of the following signs of infection including fever, chills, or a cough that does not go away. Signs of herpes include cold sores, shingles, genital sores, skin rash, pain, and itching. Signs of more serious herpes infection include: changes in vision, eye redness or eye pain, severe or persistent headache, stiff neck, and confusion. Signs of infection can happen during treatment or after you have received your last dose of Ocrevus. Tell your healthcare provider right away if you have an infection. Your healthcare provider should delay your treatment with Ocrevus until your infection is gone.
  - Hepatitis B virus (HBV) reactivation: Before starting treatment with Ocrevus, your healthcare provider will do blood tests to check for hepatitis B viral infection. If you have ever had hepatitis B virus infection, the hepatitis B virus may become active again during or after treatment with Ocrevus. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure or death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop receiving Ocrevus.
  - Weakened immune system: Ocrevus taken before or after other medicines that weaken the immune system could increase your risk of getting infections.
- Progressive Multifocal Leukoencephalopathy (PML): PML is a rare brain infection that usually leads to death or severe disability, and has been reported with Ocrevus. Symptoms of PML get worse over days to weeks. It is important that you call your healthcare provider right away if you have any new or worsening neurologic signs or symptoms that have lasted several days, including problems with:
  - thinking
  - eyesight
  - strength
  - balance
  - weakness on 1 side of your body
  - using your arms or legs
- Decreased immunoglobulins: Ocrevus may cause a decrease in some types of immunoglobulins. Your

healthcare provider will do blood tests to check your blood immunoglobulin levels.

Before receiving Ocrevus, tell your healthcare provider about all of your medical conditions, including if you:

- have ever taken, take, or plan to take medicines that affect your immune system, or other treatments for MS.
- have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have had a recent vaccination or are scheduled to receive any vaccinations.
    - You should receive any required "live" or "live-attenuated" vaccines at least 4 weeks before you start treatment with Ocrevus. You should not receive "live" or "live-attenuated" vaccines while you are being treated with Ocrevus and until your healthcare provider tells you that your immune system is no longer weakened.
    - When possible, you should receive any "non-live" vaccines at least 2 weeks before you start treatment with Ocrevus. If you would like to receive any non-live (inactivated) vaccines, including the seasonal flu vaccine, while you are being treated with Ocrevus, talk to your healthcare provider.
    - If you have a baby and you received Ocrevus during your pregnancy, it is important to tell your baby's healthcare provider about receiving Ocrevus so they can decide when your baby should be vaccinated.
- are pregnant, think that you might be pregnant, or plan to become pregnant. It is not known if Ocrevus will harm your unborn baby. You should use birth control (contraception) during treatment with Ocrevus and for 6 months after your last infusion of Ocrevus. Talk with your healthcare provider about what birth control method is right for you during this time.
    - Pregnancy Registry. There is a pregnancy registry for women who take Ocrevus during pregnancy. If you become pregnant while receiving Ocrevus, tell your healthcare provider right away. Talk to your healthcare provider about registering with the Ocrevus Pregnancy Registry. The purpose of this registry is to collect information about your health and your baby's health. Your healthcare provider can enroll you in this registry by calling 1-833-872-4370 or visiting **http://www.ocrevuspregnancyregistry.com**.
- are breastfeeding or plan to breastfeed. It is not known if Ocrevus passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take Ocrevus.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of Ocrevus?

Ocrevus may cause serious side effects, including:

- Risk of cancers (malignancies) including breast cancer. Follow your healthcare provider's instructions about

standard screening guidelines for breast cancer.

- Inflammation of the colon, or colitis: Tell your healthcare provider if you have any symptoms of colitis, such as:
    - Diarrhea (loose stools) or more frequent bowel movements than usual
    - Stools that are black, tarry, sticky or have blood or mucus
    - Severe stomach-area (abdomen) pain or tenderness

These are not all the possible side effects of Ocrevus.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

For more information, go to **https://www.Ocrevus.com** or call 1-844-627-3887.

Please see additional Important Safety Information throughout and click here for the full **Prescribing Information** and **Medication Guide**.

Indications and Important Safety Information

What is Enspryng?

Enspryng is a prescription medicine used to treat neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4 (AQP4) antibody positive. It is not known if Enspryng is safe and effective in children.

Who should not receive Enspryng?

Patients should not take Enspryng if they:

- are allergic to satralizumab-mwge or any of the ingredients in Enspryng
- have an active hepatitis B infection
- have active or untreated inactive (latent) tuberculosis (TB)

Enspryng may cause serious side effects including:

- Infections. Enspryng can increase risk of serious infections some of which can be life-threatening. Patients should speak with their healthcare provider if they are being treated for an infection and call right away if there are signs of an infection, with or without a fever, such as:
    - chills, feeling tired, muscle aches, cough that will not go away or a sore throat
    - skin redness, swelling, tenderness, pain or sores on the body

    - diarrhea, belly pain, or feeling sick
    - burning when urinating or urinating more often than usual
    - A healthcare provider will check for infection and treat it if needed before starting or continuing to take Enspryng
    - A healthcare provider should test for hepatitis and TB before initiating Enspryng
    - All required vaccinations should be completed before starting Enspryng. People using Enspryng should not be given “live” or “live-attenuated” vaccines. “Live” or “live-attenuated” vaccines should be given at least 4 weeks before a patient starts Enspryng. A healthcare provider may recommend that a patient receive a “non-live” (inactivated) vaccine, such as some of the seasonal flu vaccines. If a patient plans to get a “non-live” (inactivated) vaccine it should be given, whenever possible, at least 2 weeks before starting Enspryng

- Increased liver enzymes. A healthcare provider should order blood tests to check patient liver enzymes before and while taking Enspryng. A healthcare provider will dictate how often these blood tests are needed. Patients should complete all follow-up blood tests as ordered by a healthcare provider. A healthcare provider may wait to start Enspryng if liver enzymes are increased
- Low neutrophil count. Enspryng can cause a decrease in neutrophil counts in the blood. Neutrophils are white blood cells that help the body fight off bacterial infections. A healthcare provider should order blood tests to check neutrophil counts while a patient is taking Enspryng.
- Serious allergic reactions that may be life-threatening have happened with other medicines like Enspryng. Patients should call their healthcare provider right away if they have any of these symptoms of an allergic reaction:
    - shortness of breath or trouble breathing
    - swelling of lips, face, or tongue
    - dizziness or feeling faint
    - moderate or severe stomach (abdominal) pain or vomiting
    - chest pain

Before taking Enspryng, patients should tell their healthcare provider about all of their medical conditions, including if they:

- have or think they have an infection
- have liver problems
- have ever had hepatitis B or are a carrier of the hepatitis B virus
- have had or have been in contact with someone with TB
- have had a recent vaccination or are scheduled to receive any vaccination
- are pregnant, think they might be pregnant, or plan to become pregnant. It is not known if Enspryng will harm

one's unborn baby
- are breastfeeding or plan to breastfeed. It is not known if Enspryng passes into breast milk. Patients should speak with their healthcare provider about the best way to feed one's baby while on treatment with Enspryng

Patients should tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Enspryng include:

- sore throat, runny nose (nasopharyngitis)
- headache
- upper respiratory tract infection
- rash
- fatigue
- nausea
- extremity pain
- inflammation of the stomach lining
- joint pain

For more information about the risk and benefit profile of Enspryng, patients should ask their healthcare provider.

Patients may report side effects to the FDA at 1-800-FDA-1088 or **http://www.fda.gov/medwatch**. Patients may also report side effects to Genentech at 1-888-835-2555.

Please see the full **Prescribing Information** for additional Important Safety Information.

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Source: Genentech