Patient Assistance Program Application for Caprelsa® (vandetanib tablets)

Important Safety Information, Including Boxed WARNING, for CAPRELSA

WARNING: QT PROLONGATION, TORSADES DE POINTES, AND SUDDEN DEATH

CAPRELSA can prolong the QT interval. Torsades de pointes and sudden death have occurred in patients receiving CAPRELSA. Do not use CAPRELSA in patients with hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome. Correct hypocalcemia, hypokalemia and/or hypomagnesemia prior to CAPRELSA administration. Monitor electrolytes periodically. Avoid drugs known to prolong the QT interval. Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA.

WARNINGS AND PRECAUTIONS

QT Prolongation and Torsades de Pointes:

- Do not use in patients with congenital long QT syndrome.
- CAPRELSA can prolong the QT interval in a concentration-dependent manner. Torsades de pointes, ventricular tachycardia and sudden deaths have occurred in patients treated with CAPRELSA
- Do not start CAPRELSA treatment in patients whose QTcF interval (corrected QT interval, Fridericia) is greater than 450 ms or who have a history of Torsades de pointes, bradyarrhythmias, or uncompensated heart failure. CAPRELSA has not been studied in patients with ventricular arrhythmias or recent myocardial infarction
- Stop CAPRELSA in patients who develop a QTcF greater than 500 ms until QTcF returns to less than 450 ms. Dosing of CAPRELSA can then be resumed at a reduced dose
- Because of the risk of QT prolongation, obtain an ECG and serum potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH) at baseline, 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter. Following any dose reduction or interruptions greater than 2 weeks, conduct QT assessments as described above

Severe Skin Reactions: Severe skin reactions (including Stevens-Johnson syndrome and Toxic Epidermal Necrolysis), some leading to death, have occurred in patients treated with CAPRELSA. For severe skin reactions, refer patients for urgent medical advice. Systemic therapies e.g., steroids, may be appropriate in such cases and permanent discontinuation of CAPRELSA is recommended. Photosensitivity reactions can occur during CAPRELSA treatment and up to 4 months after treatment discontinuation

Interstitial Lung Disease (ILD): ILD or pneumonitis, including fatalities, has occurred in patients treated with CAPRELSA. Interrupt CAPRELSA for acute or worsening pulmonary symptoms and discontinue CAPRELSA if ILD is confirmed

Ischemic cerebrovascular events: Ischemic cerebrovascular events, including fatalities, occurred in patients treated with CAPRELSA. The safety of resumption of CAPRELSA therapy after resolution of an

ischemic cerebrovascular event has not been studied. Discontinue CAPRELSA in patients who experience a severe ischemic cerebrovascular event

Hemorrhage: Serious hemorrhagic events, including fatalities, occurred in patients treated with CAPRELSA. Do not administer CAPRELSA to patients with a recent history of hemoptysis of ≥1/2 teaspoon of red blood. Discontinue CAPRELSA in patients with severe hemorrhage

Heart Failure: Heart failure, including fatalities, occurred in patients treated with CAPRELSA. Monitor for signs and symptoms of heart failure. Consider discontinuation of CAPRELSA in patients with heart failure. Heart failure may not be reversible upon stopping CAPRELSA

Diarrhea: Diarrhea of Grade 3 or greater severity occurred in patients receiving CAPRELSA. If diarrhea occurs, carefully monitor serum electrolytes and ECGs to enable early detection of QT prolongation resulting from dehydration. Interrupt CAPRELSA for severe diarrhea and upon improvement resume CAPRELSA at a reduced dose

Hypothyroidism: Increased dosing of thyroid replacement therapy was required in 49% of CAPRELSA-treated patients. Obtain TSH at baseline, at 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter. If signs or symptoms of hypothyroidism occur, examine thyroid hormone levels and adjust thyroid replacement therapy accordingly

Hypertension: Hypertension, including hypertensive crisis, has occurred in patients treated with CAPRELSA. Monitor all patients for hypertension. Dose reduction or interruption for hypertension may be necessary. If hypertension cannot be controlled, do not resume CAPRELSA

Reversible posterior leukoencephalopathy syndrome (RPLS): RPLS has occurred in patients treated with CAPRELSA. Consider this syndrome in any patient presenting with seizures, headache, visual disturbances, confusion or altered mental function. In clinical studies, three of four patients who developed RPLS while taking CAPRELSA also had hypertension. Discontinue CAPRELSA treatment in patients with RPLS

Drug Interactions: Avoid administration of CAPRELSA with anti-arrhythmic drugs and other drugs that may prolong the QT interval

Renal Failure: Renal failure has occurred in patients treated with CAPRELSA. Vandetanib exposure is increased in patients with impaired renal function. Reduce the starting dose to 200 mg in patients with moderate renal impairment and monitor the QT interval closely. Vandetanib is not recommended for use in patients with severe renal impairment (clearance below 30 mL/min). There is no information available for patients with end-stage renal disease requiring dialysis

Hepatic Impairment: CAPRELSA is not recommended for patients with moderate and severe hepatic impairment, as safety and efficacy have not been established

Impaired Wound Healing: Impaired wound healing has occurred in patients treated with CAPRELSA. Withhold for at least 1 month prior to elective surgery. Do not administer CAPRELSA for at least 2 weeks

following major surgery and until adequate wound healing. The safety of resumption of treatment with CAPRELSA after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: CAPRELSA can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should avoid pregnancy and be advised that they must use effective contraception during CAPRELSA treatment and for at least 4 months following the last dose of CAPRELSA

CAPRELSA REMS Program: Because of the risks of QT prolongation, Torsades de pointes, and sudden death, CAPRELSA is available only through the CAPRELSA Risk Evaluation Mitigation Strategy (REMS) Program. Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA. To learn about the specific REMS requirements and to enroll in the CAPRELSA REMS Program, call **1-800-817-2722 or visit** www.caprelsarems.com

ADVERSE REACTIONS

The most commonly reported adverse drug reactions (>20%) seen with CAPRELSA and with a between arm difference of ≥5% are diarrhea/colitis (57%), rash (53%), acneiform dermatitis (35%), hypertension (33%), nausea (33%), headache (26%), upper respiratory tract infections (23%), decreased appetite (21%), and abdominal pain (21%)

INDICATIONS AND USAGE

CAPRELSA is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Use CAPRELSA in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA.

Please see full Prescribing Information for CAPRELSA, including Boxed WARNING.

Patient Assistance Program Application
CAPRELSA® (vandetanib) Tablets

Please return completed application by fax

Phone: 800-367-4999 (M-F, 9:00am-6:00pm Eastern Time) Fax: 888-275-8593 Website: www.caprelsa.com

(The patient must complete this application, with assistance from their physician who must sign this form, to be considered for assistance through Patient Assistance Program)

Please complete all applicable sections. This application cannot be processed without applicable signatures.

Sanofi Genzyme's Patient Assistance Program provides drug at no cost to eligible patients who are uninsured or underinsured. If approved, shipment will be coordinated with the requesting physician. This is not a replacement program; applications must be submitted prior to CAPRELSA use. CAPRELSA provided for use by this program is not intended for resale or to be billed to any patient or third party payer, including Medicare and Medicaid. This program is not meant to induce a physician to use or prescribe CAPRELSA. The program provides drug only; patients would need to find alternative means to support other medical costs associated with the use of this medication. Sanofi Genzyme reserves the right to review patient profiles, grant requests based on patient need and to change program guidelines or terminate the program at any time without notification.

PATIENT INFORMATION		
First Name:	Middle Initial: Last Name:	
Date of Birth:	Gender: ❑Male ❑Female	
Contact Name *(if other than patient):*	Contact Phone Number:	Email:
Street Address:		Apt. #:
City:	State:	Zip Code:

MEDICAL INFORMATION

Diagnosis: *Advanced or Metastatic Medullary Thyroid Cancer*

Please Check Appropriate Indication:

❑ Symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.

-OR-

❑ Indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA

❑ ICD-10 Code: C73 ❑Other

PATIENT ELIGIBILITY

Is the patient a resident of the United States or a US Territory? ❑Yes ❑No

Does patient have health insurance? ❑Yes ❑No

If patient has health insurance, has coverage for CAPRELSA been denied? (If Yes, please attach copy of denial letter) ❑Yes ❑No

INSURANCE DETAILS

(Complete section below OR attach copies of front and back of insurance cards. If no insurance, move to next section.)

Primary Insurance:	Secondary Insurance:
Policy #: Group #:	Policy #: Group #:
Insurance Company Phone:	Insurance Company Phone:
Policy Holder Name:	Policy Holder Name:
Policy Holder Date of Birth:	Policy Holder Date of Birth:

Patient Assistance Program Application for CAPRELSA (Continued)

Please return completed application by fax

Phone: 800-367-4999 (M – F, 9:00am – 6:00pm Eastern Time) Fax: 888-275-8593 Website: www.caprelsa.com

(Physician must complete application for patient to be considered for assistance through Patient Assistance Program)

Please complete all applicable sections. This application cannot be processed without applicable signatures.

Patient Name:	**DOB:**

PROVIDER and SHIPPING INFORMATION

Prescriber Name:			
NPI #:	DEA#:	Tax ID#:	
Prescriber Specialty: ❑Oncology	❑Endocrinology	❑Surgery	❑Other:
Facility / Group Name:			
Phone:	Fax:	Email:	
Street Address:			
City:	State:	Zip Code:	
Shipping Details *(Check if patient address is the same as listed Patient Information Section)*			
Patient Name:			
Street Address:			
City:	State:	Zip Code:	
Phone Number:	Ok to leave a message: ❑Yes ❑No	Email:	

PRESCRIPTION FOR CAPRELSA®

Please complete all fields. Illegible Rx will be returned.

Prescriber:			
Medication/Strength:	Directions:	QTY:	Refills: 0 – 1 – 2 – 3 ❑1 year
Medication/Strength:	Directions:	QTY:	Refills: 0 – 1 – 2 – 3 ❑1 year
PRESCRIBER SIGNATURE:			

CERTIFICATION AND CONSENT (Signatures and Dates Required)

PRESCRIBER

I certify that the information provided is current, complete, and accurate to the best of my knowledge. I certify that CAPRELSA is medically necessary for this patient and that I will be supervising the patient's treatments. I certify that I have obtained from my patient all required written authorizations, in accordance with State and Federal law for the disclosure of the information provided above to Biologics and Sanofi Genzyme for the purposes of assessing patient's eligibility for participation in the Patient Assistance Program, including verifying my patient's insurance coverage, facilitating prior authorization if needed, coordinating shipment of CAPRELSA, or referring patient to other programs or alternate sources of funding or coverage for CAPRELSA. I understand that submitting an application to the Patient Assistance Program does not guarantee that assistance will be obtained. By signing this document, I attest that the financial information I have provided is complete and accurate. If at any time it is deemed necessary to audit the patient's financial information, I will provide supportive documentation to Biologics. I agree that I will not submit claims or otherwise seek payment from any source for product provided through the patient assistance program. I understand that Biologics and Sanofi Genzyme have the right to revise, change, or terminate this Program (and the assistance provided) at any time, without notice.

PRESCRIBER SIGNATURE: _____ **DATE:** _____

PATIENT or PATIENT REPRESENTATIVE: _____

I certify that the information provided is current, complete, and accurate to the best of my knowledge. By signing below, I consent to my participation in the Patient Assistance Program and request that Biologics, Sanofi Genzyme, their affiliated companies, agents, representatives and contractors use the information in this form and any supportive documentation that is provided to support this request to assess my eligibility for participation in the patient assistance program, including verifying my insurance coverage and facilitating prior authorization if needed, and to refer me to, or determine my eligibility for, other programs or alternate sources of funding assistance or coverage that may be available to assist me with the costs of my treatment. I understand that Biologics, Sanofi Genzyme, have the right to revise, change, or terminate this program (and the assistance provided) at any time, without notice.

PATIENT SIGNATURE: _____ **DATE:** _____

PATIENT REPRESENTATIVE: _____ **DATE:** _____

RELATION TO PATIENT: _____

Please see full prescribing information for CAPRELSA, including Boxed WARNING

Support Services Authorization

I am registering for a Sanofi Genzyme support service (the "Program"), provided by Genzyme Corporation (together with its affiliates, "Sanofi Genzyme"), which offers the following services related to my medical condition ("Disease") and my Sanofi Genzyme therapy ("Therapy") (collectively, the "Services"):

Caprelsa® (vandetanib) Tablets

Education: providing educational support and resources about my Disease and its management to me and others who may benefit, which may include periodic communications from Sanofi Genzyme.

Benefits Verification: helping me get access to my Therapy and related services ordered by my Provider, which may include reviewing, verifying and helping me and my Providers understand my insurance benefits.

Reimbursement Support: helping me, and coordinating with my Providers on my behalf, with respect to billing, reimbursement and payment issues related to my Therapy, which may include assisting with the insurance claims process and identifying other potential sources of financial assistance, if necessary.

Distribution of Therapy: coordinating the distribution of my Therapy, which may include identifying the appropriate distribution channel under my insurance plan, facilitating the correct amount of Therapy to be sent to my Distributor or Provider at the time required, assisting with the prior authorization process, tracking shipments and inventory of my Therapy, and tracking dose and compliance with my prescribed treatment schedule.

By signing this Support Services Authorization, I authorize Sanofi Genzyme and its third party business partners, vendors and other agents ("Agents") to provide me with the Services. I agree that Sanofi Genzyme and its Agents may use and share information about me with my Providers, Caregivers, Payers, PAGs and Distributors for the purpose of providing the Services.

I further authorize Sanofi Genzyme and its Agents to de-identify my information and use it performing clinical research, business analytics, marketing studies or for other commercial or educational purposes.

I further authorize Sanofi Genzyme and its Agents to de-identify my health information and use it for Caprelsa Risk Evaluation and Mitigation Strategy (REMS) reporting purposes.

I understand that I do not have to register for the Program and that, if I choose not to register, I can still receive Therapy as prescribed by my physician. I may cancel the Support Services Authorization at any time by writing to the Caprelsa Access Support Program, 11800 Weston Parkway, Cary, NC 27513.

Communications with Sanofi Genzyme and Third Parties: By signing this Support Services Authorization, I also authorize Sanofi Genzyme and its Agents to contact me (or my legal representative) by mail, telephone or email, to provide me information directly or indirectly related to my Disease, Therapy, the Program or the Services ("Sanofi Genzyme Communications").

I further authorize Sanofi Genzyme and its Agents to provide my contact information to select organizations so that they may provide me with additional information or materials on behalf of Sanofi Genzyme that are directly or indirectly related to my Disease, Therapy, the Program or the Services, including, but not limited to, information on disease education/management, treatment protocols or disease-related surveys ("Third Party Communications").

Additional Information: By signing this Support Services Authorization and to the extent I have checked the boxes below, I further authorize Sanofi Genzyme and its Agents to contact me (or my legal representative) by mobile or home telephone number and email, as applicable, to send me offers, promotions, and other marketing communications, and mobile service commercial messages, regarding Sanofi Genzyme products, programs and services (collectively, "Additional Information"). I understand that my consent to this Support Services Authorization is not a condition for the purchase or receipt of any products or services from Sanofi Genzyme.

Verifications and Consents: By signing the Services Authorization below, I verify that I am the subscriber or customary user with respect to the home and mobile telephone numbers that I set forth below in the "Patient Information" section and that I have the authority to provide consent, as selected below, to receive the Sanofi Genzyme Communications, Third Party Communications, and Additional Information at those numbers and address. I also verify that I have the authority to provide consent to receive Sanofi Genzyme Communications and Third Party Communications at the **work telephone number** set forth below in the "Patient Information" section.

❑ By checking this box and signing the Support Services Authorization below, I consent to receive commercial calls at the **mobile phone number** provided below in the "Patient Information" section.

I understand that message and data rates may be assessed by my wireless provider for communications to my mobile phone or wireless device.

❑ By checking this box and signing the Support Services Authorization below, I consent to receive commercial calls at the **home phone number** provided below in the "Patient Information" section.

Opt-Out of Certain Communications: I understand that I may opt-out of receiving communcations by home phone, mobile or wireless device, work phone, or email, as applicable, at any time by providing written notice to Caprelsa Access Support Program, 11800 Weston Parkway, Cary, NC 27513.

By signing below, I certify that I have read and understand the Support Services Authorization above and agree to its terms.

Signature: _____ Date: _____

Complete the following only if the person signing and completing this Support Services Authorization is not the Patient.		
Patient's Legal Representative:		
Relationship to Patient: ❑ Custodial Parent ❑ Legal Guardian ❑ Other, please explain:		
PATIENT INFORMATION		
Name:		
Date of Birth: (MM/DD/YYYY)		
Street Address:		
City:	**State:**	**Zip Code:**
Email:		
Home Phone:		❑ Preferred Number
Work Phone:		❑ Preferred Number
Mobile Phone		❑ Preferred Number

If you sign the Support Services Authorization above, you authorize Sanofi Genzyme, its Agents and certain third parties to contact you (or your legal representative) at the home, work and mobile phone numbers or email you provide here in order to send you Sanofi Genzyme Communications, Third Party Communications, and, to the extent selected by you above, Additional Information.

I authorize Sanofi Genzyme and its Agents to discuss the Patient's Information with the following designated individual(s) in connection with the Services (optional):

Name	**Relationship to Patient**
Phone	
Email	
Name	**Relationship to Patient**
Phone	
Email	
Name	**Relationship to Patient**
Phone	
Email	
Name	**Relationship to Patient**
Phone	
Email	

Authorization to Release Health Information

By signing this Authorization to Release Health Information ("Authorization"), I authorize my Providers, Payers, Caregivers, and Distributors (collectively, the "Parties") to disclose to Sanofi, and its affiliates and agents, health information about me, including patient-related information provided throughout this form and related to my medical condition, treatment with prescribed Sanofi therapies, health insurance coverage, claims, and prescriptions (together, "My Information"). My healthcare providers, specialty pharmacies, and Sanofi(including its agents and affiliates) may use and disclose My Information for the purposes of providing certain support services, including benefit verification and drug fulfillment. Once my Information has been disclosed to Sanofi, I understand that federal privacy laws may no longer protect it from further disclosure. However, Sanofi agrees to protect My Information by using and disclosing it only for the purposes authorized in this Authorization or as otherwise required by law. I understand that I may have certain rights under applicable data privacy laws regarding My information, including the right to access My information held by Sanofi. For further information regarding these rights, please reference the Sanofi's Global Privacy Policy at https://www.sanofi.com/en/our-responsibility/sanofi-global-privacy-policy

I understand that I may refuse to sign this Authorization, that I may refuse to disclose all or some of my information, and that a refusal to sign will not affect my ability to obtain medical care, insurance coverage or access to health benefits, including access to Therapy. However, if I do not sign this Authorization and check the box regarding my health information below, Sanofi Genzyme cannot provide me with the Services. This Authorization shall remain in effect throughout my participation in the Program unless and until I cancel it; provided, however, that if I am a Minnesota resident, this Authorization is effective for one year. I may cancel this Authorization at any time by writing to the Caprelsa Access Support Program, 11800 Weston Parkway, Cary, NC 27513.

I understand that cancelling this Authorization will end my ability to receive the Services but will not affect any disclosure, acquisition, retention or use of my Information made before my request for cancellation is received and processed.

By signing below, I certify that I have read and understand the Authorization to Release Health Information and agree to its terms. I understand that I am entitled to a copy of this Authorization upon request.

❑ **I consent for the Parties and Sanofi Genzyme and its Agents to disclose, obtain, retain and use my Information as described above.**

Signature:_____ Date: _____

Print name: _____

Please return your completed Form to the Caprelsa Access Support Program.
1-800-367-4999 • Monday-Friday 9am-6pm ET • Fax 1-888-275-8593