Nintedanib* (BIBF 1120) is an investigational orally-administered triple angiokinase inhibitor that targets three of the receptor tyrosine kinases shown to aid in the regulation of angiogenesis: fibroblast growth factor receptor (FGFR), platelet-derived growth factor receptor (PDGFR), and vascular endothelial growth factor receptor (VEGFR).

Nintedanib is being evaluated in various solid tumors – including advanced non-small cell lung (NSCLC), ovarian, liver (hepatic cell carcinoma), kidney (renal cell carcinoma) and colorectal. The advanced NSCLC and ovarian cancer clinical trials are in Phase III development.

Beyond oncology, nintedanib is also being investigated in the respiratory therapeutic area and is in Phase III development for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive and fatal lung disease.

The nintedanib Phase III oncology clinical development program consists of three clinical studies:

**LUME-Lung 1 (Clinical Trial Identifier NCT00805194)**
Investigating nintedanib in combination with a standard second-line chemotherapy (docetaxel) in patients with locally advanced and/or metastatic (stage IIIB/IV) or recurrent NSCLC after failure of first-line chemotherapy.

**LUME-Lung 2 (Clinical Trial Identifier NCT00806819)**
Investigating nintedanib in combination with standard chemotherapy (pemetrexed) in patients with advanced (stage IIIB/IV) or recurrent NSCLC after failure of first-line chemotherapy.

**LUME-Ovar 1 (Clinical Trial Identifier NCT01015118)**
Investigating nintedanib as a first-line treatment in combination with standard chemotherapy (carboplatin and paclitaxel) in patients with advanced ovarian cancer (stages IIB – IV).

Nintedanib is also in a Phase I and II clinical development program, including:
- Hepatocellular carcinoma trials: 1199.37 (NCT01004003), 1199.39 (NCT00987935)
- Renal cell carcinoma trial: 1199.26 (NCT01024920)
- Colorectal cancer trials: 1199.51 and 1239.2 (NCT00904839 and NCT00801294)
- Mesothelioma trial: 1199.93 (NCT01907100)

For information on all clinical trials investigating nintedanib in oncology please visit clinicaltrials.gov.

For more information about the development status of nintedanib for IPF please visit clinicaltrials.gov.

*This compound is investigational. Its safety and efficacy have not been established.*
Angiogenesis is the process of forming new blood vessels and plays a role in many important and healthy functions, such as restoring blood flow to damaged tissues. However, angiogenesis is also involved in the growth of cancerous tumors, by supplying nutrients and oxygen often referred to as tumor angiogenesis. This “tumor angiogenesis” is initiated when tumors release molecules which signal to surrounding normal/healthy host tissue encouraging the growth of new blood vessels that ultimately help “feed” and grow the tumor.

Three receptors associated with tumor angiogenesis are: VEGFR, PDGFR and FGFR. Each of these receptors plays a different role in the growth of tumors including:

- the multiplying of cancerous cells;
- helping cancerous cells resist programmed cell death (apoptosis);
- strengthening or providing stability to the cancerous cell walls;
- aiding in the ability for cancerous cells to migrate to other areas of the body.

*This compound is investigational. Its safety and efficacy have not been established.*