The pancreas is the 10th most common site of new cancers but is the 4th leading cause of cancer death, largely due to the difficulties associated with diagnosing the disease in its early stages. As a consequence, over 80% of patients present with regional spread or distant disease at the time of diagnosis (Stage III or Stage IV) and are unsuitable for surgical resection. Survival rates from the disease are among the lowest for any type of cancer with a median survival time of 4-6 months from diagnosis, a 1-year survival rate of 26% and a 5-year survival rate of only 6%. Following curative resection, median survival time increases to between 12 and 19 months.

In a market with few available therapies that exhibit limited effectiveness and a disease class still classified as “rare”, poor survival rates and lack of viable treatment options remain compelling reasons to develop new “Orphan” therapies to address this large unmet need.
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The association between pancreatic cancer and diet, alcohol consumption and smoking are discussed further in Chapter 3.

**Orphan Disease Status**

Due to the relatively low number of people affected by pancreatic cancer it is classified as an orphan or rare disease. This is defined in the US as a disease which affects fewer than 200,000 individuals, in Japan as one which affects less than 50,000 people and in the EU as affecting less than 1 in 2,000 individuals at any given time.

Orphan disease status can result in potential therapies for the treatment of pancreatic cancer being eligible for Orphan Drug Designation. This designation allows the developing company to receive tax breaks and market exclusivity on approval of the therapy. In the US, under the terms of the Orphan Drug Act, the new therapy may receive 7 years market exclusivity and is not subject to discounting under the new healthcare law. In addition the therapy is not subject to prescription drug user fee act (PDUFA) fees unless the application includes a non-orphan disease.

In addition to favourable market conditions, as the treatment options for the disease are so limited, a single pivotal phase III trial is all that is usually required for the development plan, thereby potentially significantly decreasing drug development costs.
Additional Countries

The seven major markets and BRICK region dominate the list of countries with the highest populations of pancreatic cancer patients (Figure 3). However, there are a number of other countries with substantial pancreatic cancer patient populations and proven clinical trial expertise or important pharma markets. These include Poland and the Czech Republic, which have been key clinical trial destinations for a wide range of therapy areas for over a decade. In addition, Mexico and Argentina are well-established clinical trial locations with highly concentrated patient populations.

Australia is actively selling itself as an attractive destination for clinical trials, with a relatively efficient regulatory process, a simple clinical trial notification scheme and an R&D tax credit scheme offering 45% reimbursement of R&D expenditure for eligible applicants.

Figure 3. Countries with the Highest Populations of Pancreatic Cancer Patients

Central and Eastern European countries and Scandinavia have high ASR for pancreatic cancer (Figure 4). Other notably high rates are observed in the South American countries of Uruguay and Argentina.
Immunotherapies
Immunotherapies aim to either boost the immune system or provide ready-made components of the immune system in order to target tumour cells. A variety of mechanisms are currently under investigation for the treatment of pancreatic cancer. Therapeutic vaccines activate B cells and T cells through the introduction of antigens to the immune system. Key to the process is the selection of an appropriate tumour cell target to use as an antigen to direct the immune system response. This is an area of significant activity in pancreatic cancer with three potential immunotherapies in the late stage pipeline and more in the earlier phases of research.

Signaling Pathway Inhibitors
The cell signaling pathways of tumour cells are being targeted both upstream at the receptor tyrosine kinase and downstream in the intracellular signal transduction pathways which lead to tumour growth and progression and convey the ability to evade cell death.

As well as a wide variety of targets being employed in pancreatic cancer research, a range of methods are being investigated to target these pathways. The most common of these are the small molecule inhibitors and monoclonal antibodies. However, other methods include RNAi which uses RNA to inhibit gene expression; antisense - single-stranded RNA complementary to a messenger RNA which inhibits mRNA translation by base pairing to it and physically obstructing the translation machinery; and antibody-drug conjugates which utilize an antibody to target the tumour cell and release a cytotoxic at the site of required action.

The schematic below highlights some of the key cell signaling pathways which occur in cancer cells leading to tumour growth and progression and evasion of cell death, together with some of the development pipeline therapies which target them.
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