Media release

Roche

Basel, 15 Novembe

Opening of new HIV Centre in Cambodia signifies further progress in efforts to tackle HIV/AIDS

Unique collaboration supported by Roche signifies further achievement in increasing access to HIV/AIDS treatment and care

The Cambodia Treatment Access Programme (CTAP) has provided support for a new treatment centre for people living with HIV/AIDS in the capital, Phnom Penh, as part of its on-going efforts to tackle the growing problem of HIV/AIDS. Cambodia currently has the highest recorded HIV prevalence in Asia[1], with over 170,000 people currently living with HIV/AIDS[2].

CTAP, which was established in September 2003, is a three-way partnership between:

- The Cambodian Ministry of Health
- The National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales, Australia
- Roche

This public-private partnership is one of a number of activities being supported by Roche in resource-poor settings as part of its commitment to increasing access to HIV/AIDS healthcare.

William M. Burns, Head of Roche Pharmaceuticals said: "This is a unique collaboration established to increase access to vital HIV/AIDS healthcare in Cambodia, conduct research, and train local healthcare professionals. Roche is committed to helping people in greatest need by working in partnership with others, ensuring expertise is shared and removing patents and profit as barriers to our HIV protease inhibitor medicines in Least Developed Countries. This project is one of our efforts to make a long term difference in the fight against HIV/AIDS."

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CTAP – Phnom Penh

The new treatment centre has been established to provide a range of services including counseling, clinical care, preventative treatment for opportunistic infections and HIV therapy, and has been designed to provide the framework for a comprehensive programme of training and research in HIV medicine.

Dr Mean Chhi Vun, Director of the Cambodian National Center for HIV/AIDS, Dermatology and STDs (NCHADS) comments: "Everyone involved in CTAP has played a vital role in establishing the centre and developing the treatment and training programmes. This is a real achievement that we hope will have a great impact on people living with HIV/AIDS in Cambodia. Addressing the problems of HIV/AIDS is a real challenge and it is essential that activities undertaken focus on the needs of our people living with HIV/AIDS now and in the future. The commitment and support of Roche in helping us to establish a programme that is sustainable and can have long-term benefits will make a real difference to the people of Cambodia".

Achievements of CTAP

In addition to the opening of the HIV centre, the work undertaken by the partnership has already had an impact on HIV/AIDS in Cambodia. To date, CTAP has played a role in the:

- Development and publication of Cambodian National HIV treatment Guidelines and Policies
- Development of a National HIV Care Training Programme to help expand access to quality HIV care throughout the country

Also, NCHADS and UNSW staff supported by CTAP played key roles in helping secure monies for Cambodia from the *Global Fund for AIDS, tuberculosis and malaria*. An application for fourth round funding for HIV treatment and care was successful, with a total of US $36.5m being secured for disbursement over the next five years. It is estimated that this funding will enable coverage of HIV treatment to be scaled up to 75 per cent of those in need to treatment in Cambodia.

David Cooper, Director of The National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales (UNSW), Australia, comments: "Since the beginning of the partnership, CTAP has made real advances in the area of HIV/AIDS in Cambodia, with the training of local healthcare professionals and our contribution to the National HIV programs highlighting our achievements. In establishing the clinic, we have faced a number of challenges, but with the hard work of everyone involved and the strong commitment the Cambodian

Government and Roche we have overcome these challenges and are very proud to be welcoming the first patients into the clinic."

In addition to the vital contribution for CTAP, Roche supports other treatment access programmes, such as the CARE programme in four African countries. CARE is the Cohort programme to evaluate Access to antiretRoviral treatment and Education. The programme is run in four major urban treatment centres, Côte d'Ivoire, Kenya, Senegal and Uganda. To date, 24-week results have shown that treatment success rates using highly active antiretroviral treatment (HAART) in people living with HIV/AIDS in Africa can be as high as those achieved in Western settings.

Roche Policies in Least Developed Countries

No patents for any of Roche medicines - across all disease areas - will be filed in the world's Least Developed Countries (LDCs), as defined by the UN. Roche will not file patents on new HIV/AIDS medicines in Least Developed Countries or sub-Saharan Africa. Roche will not take action in these countries against the sale or manufacture of generic versions of HIV medicines for which Roche still holds patents. Generic versions of such HIV medicines can therefore be produced in LDCs and sub-Saharan Africa without the need for a voluntary or compulsory licence.

Roche makes its HIV protease inhibitors – Invirase (saquinavir) and Viracept (nelfinavir) available at no profit prices for direct supplies from Roche Basel to LDCs and sub-Saharan Africa.

Roche no profit pricing and patent policies apply to Cambodia and to approximately two thirds of all people living with HIV/AIDS in the world.

Through its AmpliCare program Roche has been supplying HIV viral load tests at the lowest possible price to sub-Saharan Africa, South Africa, and countries defined by the United Nation as 'least developed'. AmpliCare focuses on the complete continuum of care – from testing to monitoring to education – and works to optimize efforts on a region-by-region basis. It includes flexible pricing and support of major government and private programs. Capping it off is an education program to ensure that local doctors and nurses are fully informed on the latest advances in HIV/ AIDS care.

Roche in HIV

Roche has been committed since 1985 to groundbreaking HIV research and development of innovative new HIV drugs and diagnostic technology. Roche is a founding partner of the

Accelerating Access Initiative to increase access to HIV care in the world's Least Developed Countries and sub-Saharan Africa. For more information on Roche policy and pricing of HIV protease inhibitors for these regions and research in HIV, see www.roche-hiv.com.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-intensive healthcare groups. Its core businesses are pharmaceuticals and diagnostics. As a supplier of innovative products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and transplantation and a market leader in virology. In 2003 the Pharmaceuticals Division generated 19.8 billion Swiss francs in prescription drug sales, while the Diagnostics Division posted sales of 7.4 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai.

The National Center for HIV/AIDS, STD and Dermatology, Ministry of Health, Cambodia

The National Center for HIV/AIDS, STD and Dermatology (NCHADS) is the institution within the Cambodian Ministry of Health responsible for the planning, conduct and evaluation of government health sector HIV/AIDS and STI policy and programs.

National Centre in HIV Epidemiology and Clinical Research, University of New South Wales, Australia

NCHECR is Australia's leading agency in HIV-related clinical research. It has responsibility for the coordination of Australia's national surveillance system for HIV/AIDS and for the conduct of HIV therapeutic trials. In addition to collaborations in Cambodia, it is involved in HIV research and programs throughout the Asia Pacific region.

An open day for media is being scheduled at the clinic in March, 2005. Please contact Cendrine Banerjee-Quetel (cendrine.banerjee-quetel@ketchum.com) if you would like further information.

Additional information

- National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales, Australia: www.med.unsw.edu.au/nchecr/
- Cambodian Ministry of Health: www.cambodia.gov.kh/unisql1/egov/english/ministry.detail.html?link=9
- Sustainable Development at Roche: www.roche.com/home/sustainability.htm
- Roche Pharmaceuticals in HIV/AIDS: www.roche-hiv.com
- Roche Diagnostics AmpliCare program: http://www.roche.com/pages/downloads/sustain/pdf/rochehivbro_e.pdf

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References:
[1]UNAIDS 2004 Report on the Global AIDS Epidemic, June 2004, page 28
[2]WHO/UNAIDS Epidemiological fact sheets on HIV/AIDS and sexually transmitted infections – Cambodia, 2004 update.

Media Release

Basel, 19 November 2004

US approval for breakthrough lung cancer medicine Tarceva

Targeted treatment significantly improves survival of patients with advanced lung cancer

Roche, OSI Pharmaceuticals and Genentech announced today that the US Food and Drug Administration (FDA) have approved Tarceva (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen in the United States. Tarceva is the first and only EGFR-targeted treatment to have shown a significant survival benefit in patients with NSCLC, improving survival by 42%.[1] EGFR is a key component of the human epidermal growth factor receptor pathway, which plays a role in the formation and growth of numerous cancers.

Lung cancer is the most common cancer worldwide[2] with 1.2 million new cases annually; NSCLC accounts for almost 80 percent of all these cases. Lung cancer has a particularly high morbidity and every 30 seconds[3] someone in the world dies of the disease. With very limited treatment options available, the FDA approval of Tarceva provides patients, with advanced disease, access to this much needed, novel anti-cancer drug.

Tarceva is also currently under review for marketing authorisation with the European and other health authorities.

"Tarceva is the first treatment of its kind to have shown an impressive survival benefit in patients with advanced cancers," said William M. Burns, Head of Roche Pharmaceuticals Division. "The speed of which the FDA has approved Tarceva is testimony to this. We are pleased that patients in the US will now be able to benefit from this innovative treatment and we are working closely with European and other regulatory authorities to bring this treatment to other patients as quickly as possible"

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The FDA approval was based on results from the pivotal Phase III randomised trial (BR.21) involving 731 patients, which compared Tarceva to placebo for the treatment of patients with advanced NSCLC, following failure of first or second-line chemotherapy. Patients receiving Tarceva lived significantly longer than those in the placebo arm (6.7 months vs 4.7 months), an improvement of 42%.[1] There was also a significant increase in both the length of time before patients symptoms deteriorated and the time when patients were stable, and there was no progression of their cancer. In addition, there was a 45% improvement in survival at one year and further analysis showed treatment benefit over a broad spectrum of patients.

About Tarceva

Tarceva is an investigational small molecule that targets the human epidermal growth factor receptor (HER1) pathway. HER1, also known as EGFR, is a key component of this signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva blocks tumour cell growth by inhibiting the tyrosine kinase activity of the HER1 signalling pathway inside the cell.

Similarly to the significant survival benefit in NSCLC, Tarceva has also shown survival benefit in a phase III study in locally advanced or metastatic pancreatic cancer patients. The study met its primary endpoint of improving overall survival.

Tarceva is currently being evaluated in an extensive clinical development program by a global alliance among OSI Pharmaceuticals, Genentech, and Roche. Chugai is pursuing its development and regulatory approval for the Japanese market.

Roche in Oncology

Within the last five years the Roche Group including its members Genentech in the US and Chugai in Japan has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented five products with survival benefit in different major tumour indications: Xeloda and Herceptin in advanced stage breast cancer, MabThera in non-Hodgkin's lymphoma, Avastin in colorectal carcinoma and Tarceva in non-small cell lung cancer.

In the United States Herceptin, MabThera and Avastin are marketed either by Genentech alone or together with Biogen Idec Inc. (MabThera). Outside of the United States, Roche and its Japanese partner Chugai are responsible for the marketing of these medicines.

The Roche oncology portfolio also includes NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcaemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (hairy cell and chronic myeloid leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). CERA is the most recent demonstration of the commitment to anaemia management. The Roche Group's cancer medicines generated sales of more than 5.6 billion Swiss francs in the first nine months of 2004.

Roche is developing new tests, which will have a significant impact on disease management for cancer patients in the future. With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests, we will continue to be the leaders in providing cancer focused treatments and diagnostics.

Roche Oncology has four research sites (two in the US, Germany and Japan) and four Headquarter Development sites (two in the US, UK and Switzerland).

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References
1. Shepherd, F.: A randomized placebo-controlled trial of erlotinib in patients with advanced non-small cell lung cancer (NSCLC) following failure of 1st line or or 2nd line chemotherapy. A National Cancer Institute of Canada Clinical Trials Group (NCIC). (Abstract #7022), ASCO 2004.
2. World Health Organisation, World Cancer Report, 2003.
3. www.lungcancercoalition.org/cancer_facts.html.

Further information:

- www.roche.com
- www.gene.com
- www.osip.com
- www.health-kiosk.ch

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