One of the most significant initiatives undertaken by our company to help improve access to medicines in developing countries is the MECTIZAN® (ivermectin) Donation Program.

In 1987, we announced that we would donate MECTIZAN, our medicine for the treatment of onchocerciasis (also known as river blindness), to all who needed it, for as long as needed. The MECTIZAN Donation Program is the longest-running disease-specific drug donation program and public-private partnership of its kind.

To facilitate the donation and delivery of MECTIZAN, we established a multi-sectoral partnership involving the World Health Organization (WHO), the World Bank, ministries of health, nongovernmental organizations (NGOs), and local communities. In 1988, we established the MECTIZAN Donation Program at the Task Force for Global Health, as well as the MECTIZAN Expert Committee to provide technical and scientific advice on the implementation of the program.

In 1998, the MECTIZAN Donation Program was expanded to include mass treatment for the elimination of lymphatic filariasis (LF) in African countries where onchocerciasis and lymphatic filariasis are co-endemic. In 2017, the donation of MECTIZAN was once again expanded to provide an additional 100 million treatments per year through 2025 to support the elimination of LF globally, in countries where onchocerciasis is not endemic. The most recent expansion was approved to support the WHO’s new guidelines for the elimination of LF with annual treatments of a combination of ivermectin, diethylcarbamazine citrate (DEC), and albendazole, known as “IDA” triple therapy, to at-risk populations.

ONCHOCERCIASIS

More commonly known as river blindness, onchocerciasis is transmitted through the bite of certain black flies that live near rivers, and can cause intense itching, disfiguring dermatitis, eye lesions and, eventually, blindness. At the inception of the program, the disease was one of the leading causes of preventable blindness worldwide, and approximately 130 million people were at risk for the disease.

MECTIZAN relieves the agonizing itching that accompanies the disease and halts progression toward blindness—thereby addressing characteristics of the disease that dramatically affect people’s quality of life and productivity. MECTIZAN is well suited for distribution in remote areas by community health workers through mass distribution programs. It is the only well-tolerated drug known to halt the development of river blindness.

To date, WHO has verified that river blindness has been eliminated in Colombia, Ecuador, Guatemala and Mexico. In Latin America, there remains only one area in the Amazonian jungle, on the border of Venezuela and Brazil, where disease transmission continues.

In Africa, the disease is now well controlled as a public health problem. People no longer suffer the burden and symptoms associated with the eye and skin diseases attributed to river blindness. Under the guidance of national onchocerciasis elimination committees, African countries are taking steps to eliminate the disease through capacity-building,
improvement of treatment coverage rates, monitoring and evaluation of progress, and intercountry collaboration. The
disease has been interrupted in sub-national areas of Ethiopia, Nigeria, Sudan and Uganda, with more than 5 million people
no longer requiring MECTIZAN treatment.

LYMPHATIC FILARIASIS

Lymphatic filariasis (LF) is a devastating parasitic infection spread by mosquitoes. It is caused by threadlike parasitic
worms that damage the human lymphatic system. The main symptoms are swollen limbs with thickened, hard, rough and
fissured skin, a condition known as elephantiasis, and, in men, swelling of the scrotum, called hydrocele. An annual single
dose of MECTIZAN, administered together with a second drug, albendazole (donated by GlaxoSmithKline), is the
recommended treatment in countries where onchocerciasis coexists with LF. The two diseases coexist in 29 African
countries and in Yemen. In countries where onchocerciasis is not co-endemic there are several treatment options,
including the IDA triple therapy of MECTIZAN, DEC, and albendazole.

Togo was the first country in Africa to be validated by WHO as free of LF. In addition, treatment for LF has stopped in
districts in 11 other countries, with more than 100 million people no longer needing MECTIZAN treatment.

RESPONSIBLE DONATIONS AND ADVERSE-EXPERIENCE MONITORING AND REPORTING

While side effects following treatment with MECTIZAN are rare, we have developed a rigorous program for monitoring and
reporting any adverse experiences (AEs) in the field. With the help of local NGOs, all community drug distributors and
health professionals are trained in AE detection, management and reporting. All AEs must be reported to the company,
which then reports them to drug safety and regulatory agencies in the U.S. and internationally.

The MECTIZAN Expert Committee, WHO and ministries of health also play key roles in making sure that best practices are
applied for the surveillance and management of AEs at all levels. The AE reporting form itself has been revised several
times throughout the program’s history to streamline and standardize reporting.

While much has been achieved in the efforts to control and eliminate onchocerciasis and LF, there remain a number of
additional challenges that we and our partners are committed to actively addressing.

PRODUCT DONATION COMMITMENT

To ensure a continued supply of MECTIZAN to support the activities of our program partners, we remain committed to
continuing to donate as much MECTIZAN as is necessary to eliminate river blindness globally, and to eliminate LF in Yemen
and in the African countries where the diseases coexist. This commitment was expanded in 2017, when we committed an
additional 100 million treatments per year through 2025 to accelerate the elimination of LF in countries where
onchocerciasis and LF are not co-endemic. In 2017 alone, 300 million treatments were approved and shipped to endemic
countries for the elimination of river blindness and LF.

FINANCIAL COMMITMENT

Since 1987, we have provided financial support for the MECTIZAN Donation Program, housed at the Task Force for Global
Health. Our funding covers the activities of the program’s secretariat and includes support of the MECTIZAN Expert
Committee for the technical and scientific oversight of the donation program.
To help provide the necessary ongoing technical support for country-led neglected tropical disease (NTD) programs, including support for onchocerciasis and LF elimination programs in Africa, in 2016 WHO launched the Expanded Special Program to Eliminate NTDs (ESPEN). Our company provided $250,000 in financial support to ESPEN, and worked with other partners to design the strategy which is focused on providing technical and financial support to country-led NTD elimination programs.

In 2016, our company and the MECTIZAN Donation Program made a donation of $1 million to the END Fund in support of a new initiative to foster country-led efforts in Africa to determine when treatment for river blindness can be safely stopped. The END Fund activities that we supported concluded in 2017 and resulted in expanded in-country capacity to select and implement the most relevant coverage survey methodologies and analyses needed to assess readiness to stop treatment and monitor ongoing transmission.

In further support of monitoring and evaluation efforts, and specifically to aid national programs in determining where to treat and in mapping regions where the disease has been eliminated, the company joined a consortium of partners to fund the supply of a new LF diagnostic test. Our support consisted of a five-year, $650,000 grant awarded to WHO in 2016 for the deployment of the LF test strips in countries that are actively monitoring and evaluating their progress toward elimination of the transmission of LF.

Finally, to commemorate the 30th anniversary of the MECTIZAN Donation Program, in 2017 the company provided grants totaling $300,000 to NGO partners working in conjunction with country-led efforts toward elimination of onchocerciasis and LF.

## PARTNERSHIP COMMITMENT

Beyond addressing river blindness and LF, the MECTIZAN Donation Program is a key component of the growing trend toward integrated programs addressing neglected tropical diseases (NTDs). The integration of onchocerciasis and LF efforts via the MECTIZAN Donation Program, beginning in 1998, set the foundation for many of these initiatives, and we will remain engaged with key stakeholders to help with integration of the programs where feasible. Examples of our commitment to partnership in onchocerciasis, LF, and overall NTD efforts are noted below.

Since 2000, the company has participated in the Global Alliance to Eliminate LF (GAELF), serving in the capacity of observer and providing annual financial support to ensure productive coordination of efforts among the various partners in the effort to eliminate LF.

Our company is an original signatory of the London Declaration, a collaborative effort to accelerate progress toward eliminating or controlling 10 NTDs by the end of this decade. We joined 12 other global pharmaceutical companies and many other stakeholders, including endemic-country governments, the WHO, the Bill & Melinda Gates Foundation, USAID, the U.K. Department for International Development (DFID), NGOs, and other organizations in this effort. Together with several other pharmaceutical companies, we committed to continuing or increasing our donations of medicines to treat or prevent these diseases; donors committed financial resources, and NGOs agreed to support implementation needs. The partners came together in an initiative called Uniting to Combat NTDs to track progress and identify gaps (e.g., in NTD research and additional funding) that need to be addressed in order to reach the goals of the London Declaration. In April 2017, to mark the fifth anniversary of the London Declaration, our company and other members of Uniting to Combat NTDs were recognized by the Guinness Book of World Records for achieving a new record for the most medicines donated in a 24-hour period. Learn more about the London Declaration.

Representatives from the company and the MECTIZAN Donation Program attended the 67th WHO-AFRO regional committee meeting in 2017 to discuss progress toward fighting NTDs and to advocate for a new World Health Assembly resolution calling for the elimination of the transmission of onchocerciasis.

For more information on our neglected tropical disease (NTD) research, visit Infectious Diseases.
MILESTONES AND IMPACT

An estimated 40,000 cases of blindness are prevented by the MECTIZAN Donation Program annually. In addition, the donation of MECTIZAN led to the development of CDTI (community-directed treatment with ivermectin) programs, through which trained community volunteers distribute medicines, a critical element in effective mass-treatment programs in remote areas that often lack trained health care workers. The system is currently used to distribute other health interventions including the provision of vitamin A, cataract identification, bed nets, and immunizations and treatment for other NTDs.

WHO has verified that in Latin America, river blindness has been eliminated in Colombia, Ecuador, Guatemala and Mexico. The remaining two affected countries in Latin America, Brazil and Venezuela, are continuing treatment in an area in the Amazon jungle shared by the two countries where transmission continues.

In Africa, national onchocerciasis elimination committees (NOECs) have been established in 16 of the 29 endemic countries. Under the guidance of the NOECs, MECTIZAN treatment has stopped in 15 of the 17 focus areas in Uganda, two states in Nigeria, two focus areas in Sudan, and one focus area in Ethiopia. In total, more than 5 million people no longer need treatment for onchocerciasis in these areas, which are currently completing three years of post-treatment surveillance, as recommended by the WHO.

For LF, in 2017 Togo received validation from WHO that the disease had been eliminated as a public health problem. Two other countries, Malawi and Yemen, have stopped treatment with MECTIZAN in all endemic communities and are currently conducting the post-treatment surveillance necessary for validation. In addition, more than 100 million people in sub-national regions of nine other countries no longer need MECTIZAN treatment for LF, as the transmission of the disease has been interrupted.

Performance

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<th>2013</th>
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<th>2015</th>
<th>2016</th>
<th>2017</th>
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<tr>
<td>Direct investment in the MECTIZAN® (ivermectin) Donation Program (in millions)</td>
<td>$5.50</td>
<td>$5.50</td>
<td>$5.80</td>
<td>$3.74</td>
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<tr>
<td>Total treatments approved (in millions)</td>
<td>295</td>
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<td>Treatments approved for river blindness (in millions)</td>
<td>128</td>
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<td>Treatments approved for lymphatic filariasis (LF) (in millions)</td>
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<td>Treatments approved for joint river blindness and LF programs (in millions)</td>
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<td>Countries where elimination of LF has been validated by the World Health Organization (target: 30)</td>
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<td>Latin American countries where the elimination of river blindness has been verified by the World Health Organization (target: 6)</td>
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<td>3</td>
<td>3</td>
<td>4</td>
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1. Total investment decreased due to successful completion of 8-year grant in support of the African Program for Onchocerciasis Control.