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, to all who needed it, for as long as needed. In 1998, this donation was expanded to include mass treatment for the elimination of lymphatic filariasis (LF) in African countries where onchocerciasis and lymphatic filariasis are co-endemic. 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 multisectoral partnership involving the World Health Organization (WHO), the World Bank, ministries of health, nongovernmental development organizations (NGDOs) and local communities. In 1988, we also 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. This balanced governance and organizational structure continues to support and facilitate the donation of MECTIZAN.

For more information on the MECTIZAN Donation Program, review the MDP Annual Highlights.

ONCHOCERCIASIS

More commonly known as “river blindness,” onchocerciasis is transmitted through the bite of black flies 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—two characteristics of the disease that dramatically affect the quality of life. 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.

In Africa, while the original goal of the program was to control onchocerciasis, recent evidence from the WHO indicates that elimination is now feasible in Africa. As a result, the program’s strategy shifted from disease control to disease elimination, and the partners in this program are now working toward the goals established by the WHO to eliminate both LF and onchocerciasis by 2020 and 2025, respectively.

In Latin America, where the initial goal was to eliminate onchocerciasis through regular mass treatment with MECTIZAN—so far, four out of the six originally endemic countries have stopped treatment as a result of the interruption of transmission. Colombia and Ecuador were certified free of onchocerciasis by the WHO in 2013 and 2014, respectively; Guatemala and
Mexico have submitted their requests to the WHO for certification. The remaining two countries, Brazil and Venezuela, are continuing treatment in an area in the Amazon jungle.

LYMPHATIC FILARIASIS (LF)

LF is a devastating parasitic infection spread by mosquitoes. It is caused by threadlike parasitic worms that damage the human lymphatic system. The disease is endemic in 72 countries and is currently estimated to have infected more than 120 million people, with more than 40 million incapacitated or disfigured with swelling of the limbs, breasts (lymphedema) and genitals (hydrocele). Swollen limbs also often develop dramatically thickened, hard, rough and fissured skin (elephantiasis). An annual single dose of MECTIZAN, administered with a second drug, albendazole (donated by GlaxoSmithKline), is the recommended treatment in areas where onchocerciasis coexists with LF.

In addition to providing MECTIZAN free of charge, in December 2007 we announced a donation of $25 million over eight years (2008–2015) as part of an initiative with the World Bank to fund the African Programme for Onchocerciasis Control (APOC). APOC was originally established to support the control of the disease in African countries affected by river blindness through the development of self-sustaining MECTIZAN distribution programs named CDTI (community-directed treatment with ivermectin) programs. Many of these programs have implemented at least one other health intervention in addition to MECTIZAN delivery, thereby helping countries and their partners to improve healthcare by expanding health services in these hard-to-reach communities.

“Through the donation of MECTIZAN, Merck & Co., Inc., Kenilworth, New Jersey, USA, has been a valued partner in the effort to eliminate river blindness and lymphatic filariasis. We look forward to building on our achievements to date, and to expand as needed the delivery of the donated medicine to achieve the elimination targets.”

—Dr. Ariel Pablo Mendez, Assistant Administrator for Global Health, USAID

THE LONDON DECLARATION

Our company is an original signatory of the London Declaration, a collaborative effort to accelerate progress toward eliminating or controlling 10 neglected tropical diseases (NTDs) by the end of the 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 UK Department for International Development (DFID), NGOs and other organizations in this effort. Our company joined several other pharmaceutical companies committed to continuing or increasing their donations of medicines to treat or prevent these diseases; donors committed financial resources; and NGOs agreed to support implementation needs. The partners came together under the banner of Uniting to Combat NTDs to track progress and identify gaps (e.g., NTD research, additional funding, etc.) that need to be addressed in order to reach the goals of the London Declaration. Learn more about the London Declaration. For more information on our NTD research, visit Infectious Diseases.

ADVERSE-EXPERIENCE 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 NGDOs, all field-based community distributors are trained in AE 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, ministries of health and the WHO also play key roles in making sure best practices are applied for surveillance of AEs at the community level. The AE reporting form itself has been revised several times throughout the program’s history. Currently we are working with the WHO, endemic countries and the other drug-donation programs to
develop a common AE reporting form to standardize reporting requirements.

**PERFORMANCE**

**COMMITMENTS**

While much has been achieved in the treatment and progress toward elimination of onchocerciasis (river blindness), there remain a number of additional challenges that we and our partners are actively addressing.

To ensure a continued supply of MECTIZAN® (ivermectin) to support the activities of other program partners, we remain committed to continuing to donate as much MECTIZAN as is necessary to eliminate river blindness globally and to eliminate lymphatic filariasis (LF) in African countries where the diseases coexist.

Beyond addressing river blindness and LF, the MECTIZAN Donation Program is a key component of the growing trend toward integrated programs to address Neglected Tropical Diseases (NTDs). In fact, the integration of onchocerciasis and LF efforts via the MECTIZAN Donation Program, which began in 1998, set the foundation for many of these efforts, and we will remain engaged with key stakeholders to help with integration of the programs where feasible.

As a result of our activities and of the collaboration and contributions of a wide range of committed partners, we expect to achieve the following milestones in the years ahead:

- Although we expected the transmission of river blindness in all areas of the Americas to be halted by 2013*, mass treatment is still ongoing in remote areas of Brazil and Venezuela. We continue to work toward the goal of stopping treatment in those areas in collaboration with the local program partners.
- In accordance with the goals outlined in the WHO Roadmap for Neglected Tropical Diseases, we expect the elimination of LF and river blindness by 2020 and 2025, respectively

<table>
<thead>
<tr>
<th>River Blindness and Lymphatic Filariasis (LF) Summary 2010 2011 2012 2013 2014</th>
<th>5.5</th>
<th>5.5</th>
<th>5.5</th>
<th>5.5</th>
<th>5.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct investment in the MECTIZAN Donation Program (US$M)</td>
<td>220.0270</td>
<td>226.0</td>
<td>302.0267</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Treatments approved (in millions)</td>
<td>220.0270</td>
<td>226.0</td>
<td>302.0267</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Market value of MECTIZAN donations (US$M)</td>
<td>651</td>
<td>747</td>
<td>906</td>
<td>1,092</td>
<td>861</td>
</tr>
<tr>
<td>Countries with LF elimination programs supported by the MECTIZAN Donation Program (cumulative target: 29)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Latin American countries where treatment with MECTIZAN has been stopped to allow for post-treatment surveillance and certification that the disease has been eliminated (cumulative target: 6)</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<tr>
<td>Treatments with MECTIZAN approved for river blindness (in millions)</td>
<td>100.0040</td>
<td>0166.0</td>
<td>168.0109.6</td>
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<td></td>
</tr>
<tr>
<td>Treatments with MECTIZAN approved for LF (in millions)</td>
<td>120.0130.0150.0127.0</td>
<td>147.0</td>
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</tbody>
</table>

*2013 figures have been reconciled to reflect revised field data for the MECTIZAN Donation Program.

In 2014, 109.6 million treatments were approved for river blindness (with 71.1 million of those being for both river blindness and LF) and 147 million treatments were approved for LF. To date, our company invested approximately $66 million in direct financial support for the MECTIZAN Donation Program, in addition to donating over 1.32 billion and 983 million treatments of MECTIZAN for river blindness and LF, respectively.

The donation of MECTIZAN also has led to the development of CDTI (community-directed treatment with ivermectin) programs, through which trained community volunteers distribute medicines, a critical element to effective mass-treatment programs in remote areas that often lack trained healthcare workers. CDTI strategy has been and continues to be used to distribute MECTIZAN to more than 146,000 communities in 29 countries in Africa where river blindness is a public health problem. The CDTI strategy has enabled other health and social services—such as vitamin A distribution, cataract identification, immunization campaigns, training programs for community health workers and census taking—to be introduced in often-remote communities.
IMPACT

- An estimated 40,000 cases of river blindness are prevented by the MECTIZAN Donation Program annually
- The African Program for Onchocerciasis Control (APOC) estimates that 1 million disability-adjusted life years (DALYs) per year are averted
- The impact of the MECTIZAN Donation Program extends beyond the immediate health benefits; estimates show that investments in river blindness control programs (e.g., MECTIZAN treatment and aerial spraying to control black fly populations) are helping people live not only healthier but also more productive lives
- In 2013, Colombia received verification from the World Health Organization that river blindness was eliminated, becoming the first country to achieve that milestone. Ecuador followed in 2014, and Guatemala and Mexico expect to receive verification by 2016.
- In Africa, the distribution of MECTIZAN has stopped in 16 districts in Uganda, two districts in Mali and one district in Sudan where it believed that onchocerciasis transmission has been interrupted
- For LF in African countries coendemic with onchocerciasis, in 2014, treatment was stopped in 23 implementation units (IUs) in Benin, 33 IUs in Burkina Faso, 70 IUs in Ghana, 26 IUs in Malawi, two IUs in Niger, 30 IUs in Nigeria, six IUs in Tanzania and 16 IUs in Uganda. Post-treatment surveillance is ongoing in Togo and Yemen.

APOC believes that interrupting the transmission of river blindness in the Central African Republic, the Democratic Republic of the Congo and South Sudan will be the most problematic and will require the longest time frame. Civil unrest and poor infrastructure contribute to the slow progress in these countries.