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.

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 development organizations (NGDOs) 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, 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.

Lymphatic filariasis can be found in 72 countries, and is estimated to have infected more than 120 million people.

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.

ONCHOCEIRIASIS

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.

Latin America, Colombia, Ecuador and Mexico have received verification from WHO that river blindness has been eliminated.

We congratulate Guatemala as fourth country in Latin America to achieve WHO verification of elimination of river blindness. Learn more.

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.

William C. Campbell, a retired scientist from our company's research laboratories, was jointly named the 2015 Nobel Prize winner in Physiology or Medicine with Satoshi Omura, for the discovery of avermectin, which led to our company’s development of Mectizan® (ivermectin), a treatment for river blindness (also known as onchocerciasis) in Africa, Latin America and Yemen. They shared the prize with Youyou Tu for her discoveries concerning a novel therapy for treatment of malaria.

“We are particularly proud of our colleague Dr. Campbell, whose innovation, passion and dedication to fighting diseases during his 30-year career at our company enabled the development of Mectizan. Through our Mectizan Donation Program, we have been working with partners for nearly three decades to make this medicine available, free of charge, to all those affected by river blindness. We remain committed to bringing the best that our science and innovation have to offer to solve the world’s global health challenges.”

Kenneth C. Frazier
Chairman and Chief Executive Officer
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 disease is endemic in 72 countries and is 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 together with a second drug, albendazole (donated by GlaxoSmithKline), is the recommended treatment in areas where onchocerciasis coexists with LF.

RESPONSIBLE DONATIONS AND 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 of onchocerciasis (river blindness) and progress has been made toward its elimination, 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® (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.

Since 1987, we have provided financial support for the MECTIZAN Donation Program.

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). In fact, 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.
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 secretariat and includes support of the MECTIZAN Expert Committee for the technical and scientific oversight of the donation program.

In addition to our core support for the MECTIZAN Donation Program secretariat, 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 World Health Organization’s African Program for Onchocerciasis Control (APOC). APOC was established in 1995 by the World Health Organization (WHO) to carry out a sustainable strategy to control onchocerciasis in Africa using MECTIZAN through an approach called CDTI (community-directed treatment with ivermectin).

The CDTI delivery infrastructure proven effective through APOC is also being used to deliver other health interventions including vitamin A, cataract identification, bed nets, and immunizations and treatment for other NTDs. APOC successfully concluded its activities at the end of 2015, and full responsibility for onchocerciasis control is being transferred to the ministries of health of affected countries, with the goal of establishing country-led systems capable of eliminating onchocerciasis as a public health problem in all endemic countries in Africa.

To help provide the necessary ongoing technical support for country-led neglected tropical disease (NTD) programs, including for onchocerciasis, WHO launched ESPEN (Expanded Special Program to Eliminate NTDs) in early 2016. Our company has committed financial support to ESPEN, and we were invited to join with other partners in designing the ESPEN strategy to provide technical and other resources in support of country-led NTD elimination programs.

In February of 2016, our company and the MECTIZAN Donation Program made a donation of $1M to the END Fund in support of a new initiative that will foster country-led efforts in Africa to determine when treatment for river blindness can be safely stopped. The END Fund’s activities are coordinated with ESPEN to ensure alignment among partners at the regional and country levels.

PARTNERSHIP COMMITMENT

As a reflection of our overall commitment to partnership in eliminating neglected tropical diseases (NTDs) such as onchocerciasis and 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 UK 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. Learn more about the London Declaration.

MILESTONES AND IMPACT

Latin America, Colombia, Ecuador and Mexico have received verification from the World Health Organization that river blindness has been eliminated, and Guatemala expects to receive verification in 2016. The remaining two affected countries, Brazil and Venezuela, are continuing treatment in an area in the Amazon jungle.

In Africa, while the original goal of the program was to control onchocerciasis, current research by the WHO indicates that elimination is now feasible. As a result, the program’s strategy has shifted from disease control to disease elimination, and the partners in this program are now working toward the goals established through the WHO Roadmap for Neglected Tropical Diseases, to eliminate LF and onchocerciasis by 2020 and 2025, respectively.
## RIVER BLINDNESS AND LYMPHATIC FILARIASIS (LF) SUMMARY

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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</thead>
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<tr>
<td>Direct investment in the MECTIZAN® (ivermectin) Donation Program (in millions)</td>
<td>$5.5</td>
<td>$5.5</td>
<td>$5.5</td>
<td>$5.5</td>
<td>$5.8</td>
</tr>
<tr>
<td>Total treatments approved (in millions)¹</td>
<td>233.5</td>
<td>229.0</td>
<td>295.0</td>
<td>257.0</td>
<td>176.0</td>
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<tr>
<td>Treatments approved for river blindness (in millions)</td>
<td>104</td>
<td>85</td>
<td>128</td>
<td>39</td>
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<tr>
<td>Treatments approved for lymphatic filariasis (LF) (in millions)</td>
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<td>109</td>
<td>127</td>
<td>147</td>
<td>94</td>
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<tr>
<td>Treatments approved for joint river blindness and LF programs (in millions)</td>
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<td>35</td>
<td>40</td>
<td>71</td>
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<tr>
<td>Market value of MECTIZAN donations (in millions)</td>
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<td>$906</td>
<td>$1,092</td>
<td>$861</td>
<td>$1,083</td>
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<td>Countries where treatment with MECTIZAN for LF has stopped to allow for post-treatment surveillance and validation (target = 30)²</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>3</td>
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<tr>
<td>Latin American countries where treatment with MECTIZAN has been stopped to allow for post-treatment surveillance and verification that the disease has been eliminated (target: 6)</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

¹ Additional detail from previous reports to provide more detailed breakdown of donation by disease
² New metric/target reflecting program focus on elimination efforts

In 2015, 176 million treatments with MECTIZAN were approved for onchocerciasis and LF. The decrease from 2014 is due to the timing of donation requests from countries; we continue to fulfill 100 percent of all qualified requests for MECTIZAN. To enhance our reporting, we are now breaking down our approval figures to reflect the range of programmatic uses of the donation (river blindness, LF, both). We are also adding a new metric and target related to LF elimination; counting the number of countries where treatment for LF has been stopped to allow for post-treatment validation of elimination.

### IMPACT

- Since 2013, Colombia, Ecuador and Mexico have received verification from the World Health Organization that river blindness has been eliminated, and Guatemala expects to receive verification in 2016. The remaining two affected countries, Brazil and Venezuela, are continuing treatment in an area in the Amazon jungle.
- For LF, three countries (Malawi, Togo and Yemen) have stopped treatment with MECTIZAN to allow for post-treatment surveillance and validation.
- The donation of MECTIZAN has 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.
- An estimated 40,000 cases of river blindness are prevented by the MECTIZAN Donation Program annually.

For more information on our neglected tropical disease research, visit [Infectious Diseases](#).