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.

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.

To date, WHO has verified that river blindness has been eliminated in Colombia, Ecuador, Guatemala and Mexico.

MECTIZAN relieves the agonizing itching that accompanies the disease and halts progression toward blindness—thereby
addressing 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.

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.

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 NGDOs, all field-based distributors 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, ministries of health, and WHO also play key roles in making sure that best practices are applied to surveillance and management of AEs at the community level. The AE reporting form itself has been revised several times throughout the program’s history to streamline and standardize reporting.

Impact

- Since 2013, Colombia, Ecuador, Guatemala and Mexico have received verification from the World Health Organization that river blindness has been eliminated. The remaining two affected countries in Latin America, Brazil and Venezuela, are continuing treatment in an area in the Amazon jungle.
- For LF, Togo has received verification from the World Health Organization that LF has been eliminated as a public health problem. Two other countries, Malawi and Yemen have stopped treatment with MECTIZAN in all endemic communities 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 healthcare workers.
- An estimated 40,000 cases of blindness are prevented by the MECTIZAN Donation Program annually.

For more information on our neglected tropical disease (NTD) research, visit Infectious Diseases.
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 in order 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 lymphatic filariasis in the African countries and in Yemen 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’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 lymphatic filariasis, WHO launched the Expanded Special Program to Eliminate NTDs (ESPEN) in early 2016. Our company provided $250,000 in 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 $1 million 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 the country level.
PARTNERSHIP COMMITMENT

As a reflection of our overall commitment to partnership in eliminating neglected tropical diseases (NTDs) including 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, 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, the members of Uniting to Combat NTDs were recognized by the Guinness Book of World Records for achieving the new record of the most medicines donated in a 24-hour period. Learn more about the London Declaration.

MILESTONES AND IMPACT

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.

In Africa, while the original goal of the program was to control onchocerciasis, current research by 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.

In addition, through an approach called CDTI (community-directed treatment with ivermectin), the delivery infrastructure for addressing onchocerciasis and LF is also being used to deliver other health interventions including the provision of vitamin A, cataract identification, bed nets, and immunizations and treatment for other NTDs.

RIVER BLINDNESS AND LYMPHATIC FILARIAsis (LF) SUMMARY

|--------------------------------------|-------|-------|-------|-------|-------|
| Direct investment in the MECTIZAN® (ivermectin) Donation Program (in millions)
  $5.50                                      |       |       |       |       |
| Total treatments approved (in millions) | 229   | 295   | 257   | 176   | 283   |
| Treatments approved for river blindness (in millions) | 85    | 128   | 39    | 55    | 64    |
| Treatments approved for lymphatic filariasis (LF) (in millions) | 109   | 127   | 147   | 94    | 141   |
| Treatments approved for joint river blindness and LF programs (in millions) | 35    | 40    | 71    | 27    | 78    |
| Market value of MECTIZAN donations (in millions) | $906  | $1,092 | $861  | $1,083 | $1,187 |
| Countries where elimination of LF has been validated by the World Health Organization (target = 30) | 0     | 0     | 0     | 0     | 0     |
| Latin American countries where the elimination of river blindness has been verified by the World Health Organization (target: 6) | 1     | 2     | 3     | 3     | 4     |

1. Total investment decreased due to successful completion of 8-year grant in support of the African Program for Onchocerciasis Control.

In 2016, 283 million treatments with MECTIZAN were approved for onchocerciasis and LF. 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, and...
both]. We are also adding a new metric and target related to LF elimination: counting the number of countries where LF elimination has been verified by the World Health Organization.