New drugs, new hope and possible timelines

At the recent Conference on Retroviruses and Opportunistic Infections (CROI), which took place in Seattle from February 13 to 16, 2017, researchers presented data about new anti-HIV compounds in development, including the following:

- a new integrase inhibitor – bictegravir
- a new nuke (NRTI) – code-named GS-9131
- a non-nuke (NNRTI) – doravirine
- a new protease inhibitor – code-named GS-PI1
- a capsid inhibitor (a new class of drug) – code-named GS-CA1

As all of these drugs are in development, they do not yet have brand names and in some cases they have only code names.

That these drugs are coming is good news for people who have HIV that is resistant to some medications. However, as these are all new drugs in development, they will take some time to come through the pipeline.

Timelines

The drugs that are closest to completing their final stages of clinical development are bictegravir and doravirine.

**Bictegravir**

Results from the main phase III studies of the integrase inhibitor bictegravir should become available in the latter half of 2017. The drug’s manufacturer, Gilead Sciences, will then submit a dossier about bictegravir to regulatory authorities in Canada, the European Union and the U.S. and then to other countries. It will probably take a year before regulatory agencies finish reviewing the data, which means that bictegravir is unlikely to be approved until late summer or autumn of 2018. Once approved by Health Canada, bictegravir will have to undergo other secondary reviews and then Gilead will enter into negotiations with the provinces and territories about the drug’s price and its place on their formularies (lists of subsidized medicines). Based on past trends, it is unlikely that bictegravir will be listed on formularies until sometime in the first half of 2019.

**Doravirine**

This non-nuke has completed most of the final phase of clinical trials. The doravirine dossier will hopefully be submitted by the pharmaceutical company Merck to regulatory authorities in Canada, the European Union and the U.S. later this year. Again, following past practices, it is likely that doravirine will not be approved until sometime in mid- to late 2018 and then it will probably take up to a year to be subsequently listed on provincial and territorial formularies. This means that doravirine is not likely to be on these formularies until sometime in the first half of 2019.

**The other drugs**

All of the other drugs previously mentioned are made by Gilead Sciences and are in very early stages of development. Although their development details have not been released, the nuke GS-9131 is likely to enter phase I clinical trials in 2017. Phase I clinical trials assess the safety and preliminary effectiveness of a drug. If the drug proves safe and shows effectiveness, then it will move on to phase II. If all goes well, phase III trials could begin within two to three years.

The capsid inhibitor (GS-CA1) is the most interesting of the new compounds because it is the first drug of its kind to be developed. In experiments Gilead scientists noticed that the capsid inhibitor breaks down slowly. As a result, a
long-acting formulation of the capsid inhibitor has been created. As no long-acting formulation of any anti-HIV drug has been approved, the development of the capsid inhibitor may take longer than if it were being developed as a standard formulation (immediate release). Gilead has to continue experiments with the capsid inhibitor in animals, and if those go well, phase I studies in people should hopefully begin in 2018.

The experimental protease inhibitor, code-named GS-PI1, appears to be furthest behind in the development timeline; clinical trials with this drug may not begin for several years.

In this issue of *TreatmentUpdate* we present information that was made available at CROI about these emerging therapies.

—Sean R. Hosein
Disclaimer

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