

Timeline of Key Events

1987	Gilead Sciences, Inc. (Gilead) is founded in Foster City, California.
1992	Gilead becomes a publicly traded company.
1998	Pharmasset, Inc. (Pharmasset) is founded in Tucker, Georgia.
2006	Pharmasset becomes a publicly traded company.
2008	Pharmasset spends \$770,000 researching PSI-7977, a molecule being developed for the treatment of the Hepatitis C virus (HCV). PSI-7977 would become Sovaldi.
2009	Pharmasset spends \$6.9 million researching PSI-7977.
2010	Pharmasset announces initiation of Phase 2a and 2b studies for PSI-7977. This announcement is the first public acknowledgement that the compound is being developed. The company spends \$16.4 million researching the compound.
May 13, 2011	The Food & Drug Administration (FDA) approves Vertex Pharmaceutical's Incivek (telaprevir) through priority review, for the treatment of Chronic Hepatitis C (CHC) genotype 1 in adult patients with compensated liver disease (including cirrhosis), in combination with pegylated interferon alfa and ribavirin. FDA approves Merck & Company's (Merck) Victrelis (boceprevir) through priority review, for the treatment of CHC genotype 1, in combination with pegylated interferon-alfa and ribavirin, in adult patients with compensated liver disease (including cirrhosis). These drugs are the first direct-acting antivirals (DAA) to receive FDA approval. DAAs work by targeting enzymes within the RNA of HCV.
September 2, 2011	Gilead begins negotiations to acquire Pharmasset. Gilead's initial offer is \$100 per share.
November 1, 2011	Pharmasset initiates Phase 3 trials for PSI-7977.
November 6, 2011	Pharmasset announces results of a Phase 2 trial in which all Hepatitis C (HCV) patients who used PSI-7977 were cured of the disease.
November 21, 2011	Gilead announces agreement to purchase Pharmasset for \$137 per share.
December 16, 2011	Pharmasset halts clinical trials for a second HCV drug, PSI-938. In response to the news, a Gilead spokesman tells the Wall Street Journal , "[s]ince the announcement from Pharmasset regarding PSI-938 does not impact the development of PSI-7977, we do not believe the fundamental value of the deal has been impacted."
January 17, 2012	Gilead completes its purchase of Pharmasset, Inc. for \$11.2 billion. PSI-7977 becomes GS-7977.
March 25, 2013	Gilead begins its evaluation of pricing and access for GS-7977, which would be marketed as Sovaldi.
May 6, 2013	FDA grants Viekira Pak breakthrough therapy designation.
October 10, 2013	FDA grants Sovaldi breakthrough therapy designation. The designation would allow the company to include two additional Phase 3 studies, VALLENCE and PHOTON-1, which provided data supporting treatment of genotype 3 patients, and genotype 1 patients co-infected with HIV, respectively.
November 22, 2013	FDA approves Olysio (simeprevir) through priority review, for the treatment of CHC genotype 1 as a component of a combination antiviral treatment regimen.
November 18–23, 2013	Gilead executives set the price of Sovaldi at \$84,000.
December 6, 2013	FDA approves Gilead's Sovaldi (sofosbuvir) through priority review and with breakthrough therapy designation, for the treatment of CHC infection as a component of a combination antiviral treatment regimen.

Timeline of Key Events—Continued

January 29, 2014	The American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA) issue recommendations that health care providers prescribe Sovaldi and Olysio in combination for genotype 1 patients who are not eligible to receive interferon.
July 11, 2014	Senators Wyden and Grassley send a letter to Gilead CEO John Martin seeking information about how the company priced Sovaldi.
August 11, 2014	Vertex Pharmaceuticals notifies providers it will discontinue sales of Incivek in October.
October 10, 2014	FDA approves Gilead's Harvoni (ledipasvir and sofosbuvir) through priority review and with breakthrough therapy designation, for the treatment of CHC genotype 1.
October 28, 2014	The National Association of Medicaid Directors sends letter to Congress raising concerns about the price of Sovaldi and Harvoni.
November 5, 2014	FDA approves Olysio-Sovaldi combination for treatment of patients with CHC genotype 1. The application for the combination was submitted by Johnson & Johnson.
December 19, 2014	FDA approves AbbVie Inc.'s Viekira Pack (ombitasvir, paritaprevir, and ritonavir, dasabuvir) through priority review and with breakthrough therapy designation, for use with or without ribavirin to treat patients with CHC genotype 1.
December 22, 2014	Express Scripts Holding Co., the nation's largest pharmaceutical benefits manager, announces that it has reached a deal to include Viekira Pak on its preferred drug list at a significant, but undisclosed discount. The deal sparks competition between AbbVie and Gilead.
January 20, 2015	Johnson & Johnson announces financial results for full year 2014. Sales of Olysio total \$2.3 billion, largely attributable to co-prescriptions with Sovaldi. The company reports a sharp drop in Olysio sales during the fourth quarter of 2014, compared to the third quarter, which analysts attribute to competition from Harvoni. Merck notifies providers that it will discontinue sales of Victrelis by December 2015.
February 3, 2015	Gilead announces financial results for full year 2014. Net product sales for Sovaldi total \$10.3 billion; net product sales for Harvoni total \$2.1 billion. The company announces that it expects the "gross-to-net" discount for HCV drugs to average 46% in 2015, compared to 22% in 2014. The increase is attributed to recent agreements it has reached with payers. The company also announces a \$15 billion stock buyback program, and initiates a 43-cent-per-share quarterly dividend.
March 24, 2015	FDA issues safety warning that Sovaldi and Harvoni, when used with other direct-acting antiviral drugs such as Olysio, can cause "serious slowing of the heart rate" when used with the arrhythmia drug amiodarone.
July 24, 2015	FDA approves Bristol-Meyer Squibb's Daklinza (daclatasvir) through priority review for the treatment of CHC genotype 3 in combination with Sovaldi. FDA approves AbbVie's Technivie (ombitasvir, paritaprevir, and ritonavir) through priority review and with breakthrough therapy designation, for use in combination with ribavirin for the treatment of CHC genotype 4 patients without cirrhosis.
October 22, 2015	FDA issues safety warning that Viekira Pak and Technivie can cause serious liver injury, "mostly in patients with underlying advanced liver disease."
October 27, 2015	Gilead announces third quarter financial results. For the first nine months of 2015, net product sales for Harvoni total \$10.5 billion; net product sales for Sovaldi total \$3.7 billion.

Timeline of Key Events—Continued

- October 30, 2015** AbbVie announces third quarter financial results. For the first nine months of 2015, net revenue for Viekira Pak totals \$1.1 billion.
- November 5, 2015** The Centers for Medicare & Medicaid Services (CMS) sends a letter to state Medicaid programs expressing concerns about continuing access restrictions for HCV drugs, and encouraging states to negotiate with pharmaceutical companies. On the same day, CMS sends letters to Gilead, Johnson & Johnson, AbbVie, and Merck, seeking information about the companies' negotiating practices.