#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

#### FORM 8-K CURRENT REPORT

#### Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 26, 2011 (September 25, 2011)

#### **REGENERON PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Charter)

New York

000-19034

(Commission File No.)

13-3444607 (IRS Employer Identification No.)

(State or other jurisdiction of Incorporation)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707

(Address of principal executive offices, including zip code)

(914) 347-7000

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01 Regulation FD Disclosure.

On September 25, 2011, at the European Multidisciplinary Cancer Congress in Stockholm, Sweden, data from the Phase 3 VELOUR trial evaluating the investigational agent ZALTRAP<sup>™</sup> (aflibercept), also known as VEGF Trap, in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan], versus a regimen of FOLFIRI plus placebo, were presented by Prof. Josep Tabernero. A copy of the slides that were presented is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

#### **Item 9.01** Financial Statements and Exhibits.

(d) Exhibits

99.1 Presentation entitled Results from VELOUR, a Phase 3 Study of Aflibercept Versus Placebo in Combination with FOLFIRI for the Treatment of Patients with Previously Treated Metastatic Colorectal Cancer: Results from Prespecified Subgroup Analyses.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 26, 2011

REGENERON PHARMACEUTICALS, INC.

By: <u>/s/</u> Joseph J. LaRosa Name: Joseph J. LaRosa Title: Senior Vice President, General Counsel and Secretary

Number Description	
99.1 Presentation entitled Results from VELOUR, a Phase 3 Study of Aflibercept Versus Placebo in Comb FOLFIRI for the Treatment of Patients with Previously Treated Metastatic Colorectal Cancer: Results Prespecified Subgroup Analyses.	

Results from VELOUR, a Phase 3 Study Of Aflibercept Versus Placebo In Combination With FOLFIRI For The Treatment Of Patients With Previously Treated Metastatic Colorectal Cancer

#### **Results from Prespecified Subgroup Analyses**

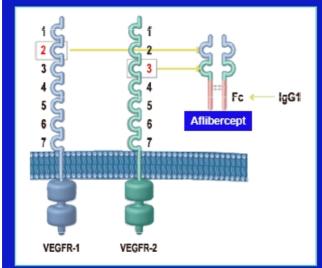
Josep Tabernero\*,

E. Van Cutsem, R. Lakomy, J. Prausova, P. Ruff, G. Van Hazel, V. Moiseyenko, D. Ferry, J. Mckendrick, K. Soussan-Lazard, E. Boelle, C. Allegra, on the behalf of the VELOUR investigators

\* Vall d'Hebron University Hospital / Barcelona/ Spain

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## Aflibercept



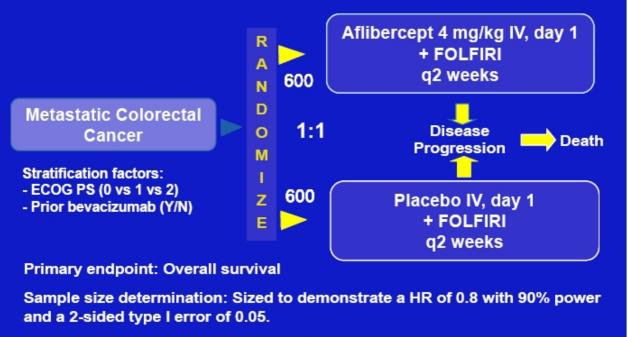
- Fusion protein of key domains from human VEGF receptors 1 and 2 with human IgG Fc<sup>1</sup>
- Blocks all human VEGF-A isoforms, VEGF-B and placental growth factor (PIGF)<sup>2</sup>
- High affinity—binds VEGF-A and PIGF more tightly than native receptors
- Contains human amino acid sequences<sup>1</sup>

1. Adapted from Holash. Proc Natl Acad Sci. 2002;99:11393–11398. 2. Adapted from Tew. Clin Cancer Res. 2010;16:358–366.

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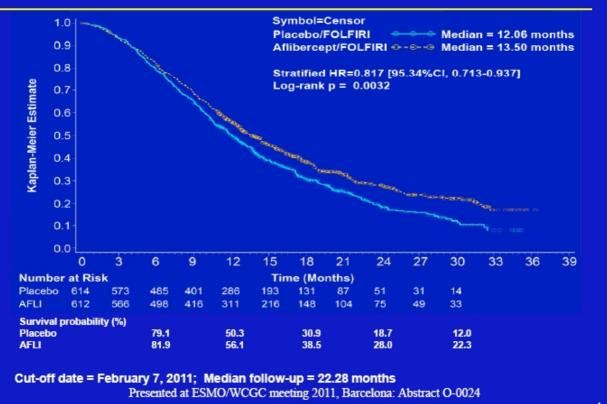
# **VELOUR Study Design**



Final analysis of OS: Analyzed at 863<sup>th</sup> death event using a 2-sided nominal significance level of 0.0466 (α spending function)

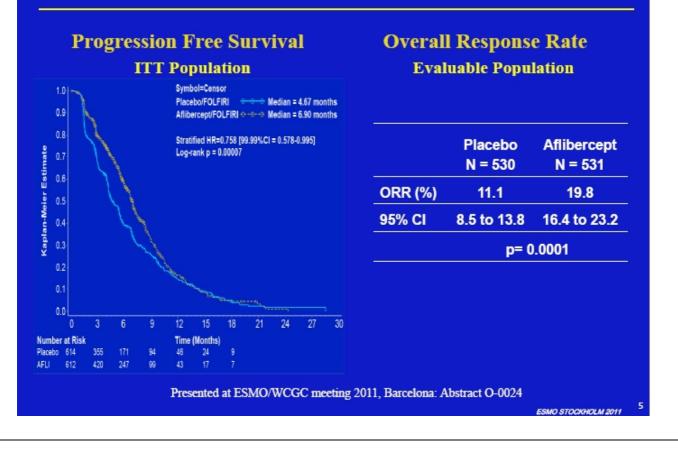
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## **Overall Survival, ITT Population**



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# **Secondary Endpoints**



# **Pre-specified Subgroup Analyses**

- <u>Goal</u>: to confirm consistency of the effect of aflibercept on OS and PFS
- <u>Methodology</u>: impact assessment on prespecified subgroups:
  - Stratification factors
    - ECOG PS, Prior bevacizumab
  - Baseline characteristics
    - · Age, gender, geographic region
    - Prior hypertension, number of metastatic sites, disease confined to liver, location of primary tumor

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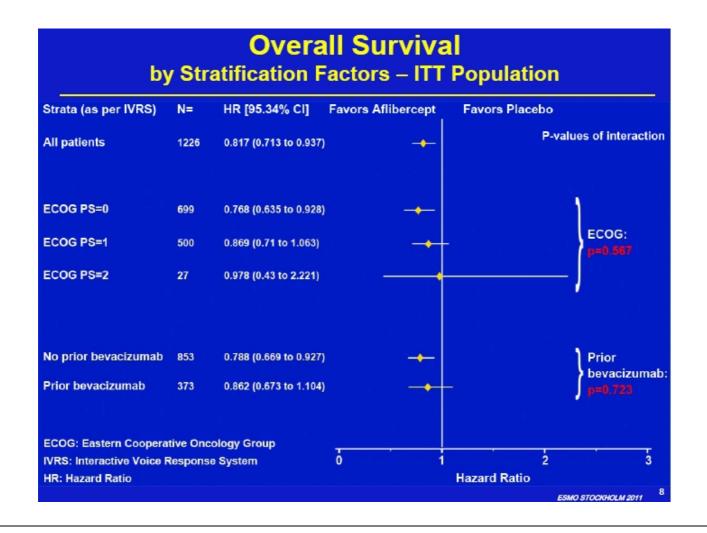
### Methodology for Prespecified Subgroups Analyses

- For each parameter, a Cox Proportional Hazard Model was used for the overall population, including the parameter, the treatment effect and the treatment by parameter interaction.
- Interactions between treatment and each subgroup were tested at the 2-sided 10% level

 ie, a p-value > 0.1 indicates no evidence of heterogeneity of treatment effect across the subgroups for each factor.

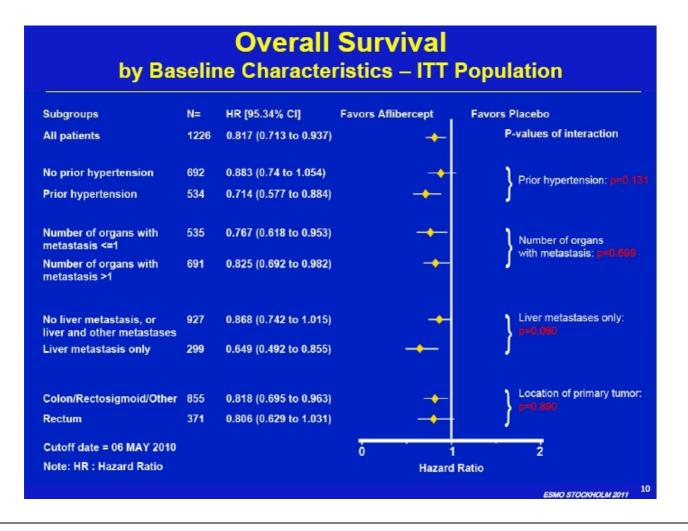
- Within each subgroup, the treatment effect hazard ratio and its (1-α)% confidence intervals were estimated using a Cox Proportional Hazard model on patients of this subgroup.
- Safety was analyzed according to prior treatment with bevacizumab

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### **Overall Survival** by Demographic Characteristics – ITT Population

Subgroups	N=	HR [95.34% CI]	Favors Aflibercept	Favors Placebo
All patients	1226	0.817 (0.713 to 0.937)	-	P-values of interaction
Age <65	783	0.796 (0.67 to 0.945)	<b></b>	} Age: p=0.683
Age >=65	443	0.853 (0.682 to 1.066)	- <b>-</b>	Age: p=0.005
Male	718	0.83 (0.696 to 0.989)	_ <b>-</b> _	
Female	508	0.776 (0.625 to 0.963)	<b></b>	} Gender: p=0.504
Western Europe	425	0.891 (0.712 to 1.114)		1
Eastern Europe	297	0.697 (0.519 to 0.934)	<b></b>	
North America	138	0.691 (0.442 to 1.079)		Region: p=0.653
South America	118	0.838 (0.53 to 1.324)		—
Other countries	248	0.891 (0.67 to 1.186)	-+	-
Cutoff date = 7 Fi	BRUA	RY 2011	0 1 0 1	2
Note: HR : Hazard	l Ratio		Hazard Ra	itio
Other countries =	Austr	alia, New Zealand, South A	frica and Korea	
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## **Progression Free Survival** by Stratification Factors – ITT Population

Strata (as per IVRS) All patients	N= 1226	HR [95% CI] 0.758 (0.661 to 0.869)	Favors Aflibercept	Favors Placebo P values of interaction
ECOG PS=0	699	0.761 (0.633 to 0.913)	<b></b>	ECOG PS:
ECOG PS=1 ECOG PS=2	500 27	0.749 (0.607 to 0.923) 0.618 (0.259 to 1.475)		p=0.496
No prior bevacizumab	853	0.797 (0.679 to 0.936)		Prior bevacizumab:
Prior bevacizumab	373	0.661 (0.512 to 0.852)		p=0.696
Cutoff date = 06 MAY 2 Note: HR : Hazard Rati			0 1 Hazard	2 Ratio ESMO STOCKHOLM 2011 <sup>11</sup>

### **Progression Free Survival** by Demographic Characteristics – ITT Population

Subgroups	N=	HR [95% CI]	Favors Aflibercept	Favors Placebo
All patients	1226	0.758 (0.661 to 0.869)	<b>—</b>	P-values of interaction
Age <65 Age >=65	783 443	0.765 (0.645 to 0.909) 0.748 (0.598 to 0.936)	- <b>-</b> -	Age: p=0.929
Age 2-03	444-3	0.740 (0.380 (0.0.830)		· ·
Male	718	0.769 (0.645 to 0.917)	<b>_</b>	Gender: p=0.742
Female	508	0.733 (0.593 to 0.908)	<b>—</b>	Sender, plant is
Western Europe	425	0.778 (0.624 to 0.97)	<b>→</b>	
Eastern Europe	297	0.688 (0.51 to 0.929)	<b></b>	
North America	138	0.536 (0.344 to 0.837)	<b>+</b>	Region: p=0.325
South America	118	0.666 (0.424 to 1.045)		
Other countries	248	0.926 (0.695 to 1.235)	+	- /
Cutoff date = 06 M	AAY 20	10	ò i	· 2
Note: HR : Hazard	l Ratio		Hazard	Ratio
Other countries =	Austr	alia, New Zealand, South A	frica and Korea	
				ESMO STOCKHOLM 2011

Subgroups	N=	HR [95% CI]	Favors Aflibercept	Favors Placebo
All patients	1226	0.758 (0.661 to 0.869)	+	P-values of interaction
No prior hypertension	692	0.736 (0.616 to 0.88)	<b>~</b>	Prior hypertension: p=0.78
Prior hypertension	534	0.761 (0.616 to 0.94)		}
Number of organs with metastasis <=1	535	0.655 (0.527 to 0.815)	<b>~</b>	Number of organs with metastasis; p=0.146
Number of organs with metastasis >1	691	0.822 (0.69 to 0.979)	-	
No liver metastasis, or liver and other metastases	927	0.839 (0.719 to 0.98)	-+-	Liver metastases only: p=0.008
Liver metastasis only	299	0.547 (0.413 to 0.725)		J
Colon/Rectosigmoid/Other	855	0.71 (0.603 to 0.836)	<b>_</b>	Location of primary tumor:
Rectum	371	0.881 (0.689 to 1.127)	· · · · · · · · · · · · · · · · · · ·	p=0.152

## Prior Treatment with Bevacizumab Number of Patients

	Placebo/FOLFIRI N=614	Aflibercept/FOLFIRI N = 612
Yes	187 (30.5%)	186 (30.4)
No	427 (69.5%)	426 (69.6%)

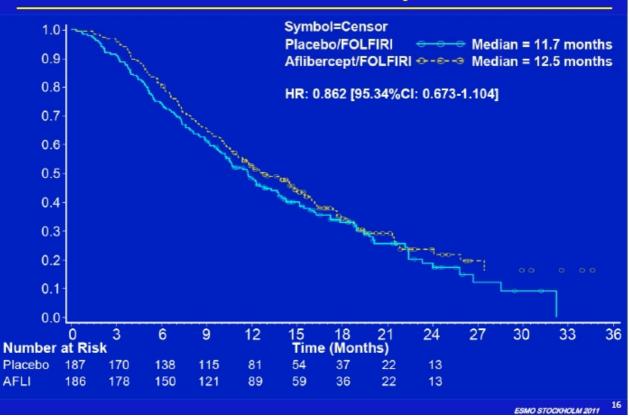
### Overall Survival: Patients with or without Prior Treatment with Bevacizumab - ITT Population

	Placebo/ FOLFIRI Median (mos) N = 614	Aflibercept/FOLFIRI Median (mos) N = 612	P-value for interaction
All Patients	12.1	13.5	All Patients
Prior BEV			
No	12.4	13.9	0.7231
Yes	11.7	12.5	

Interaction between "treatment arm" and "prior bevacizumab" factor was **not** significant at the 2-sided 10% level (p = 0.7231).

Improvement in OS was consistent regardless of prior treatment with bevacizumab

#### Overall Survival, Patients with Prior Treatment with Bevacizumab - ITT Population



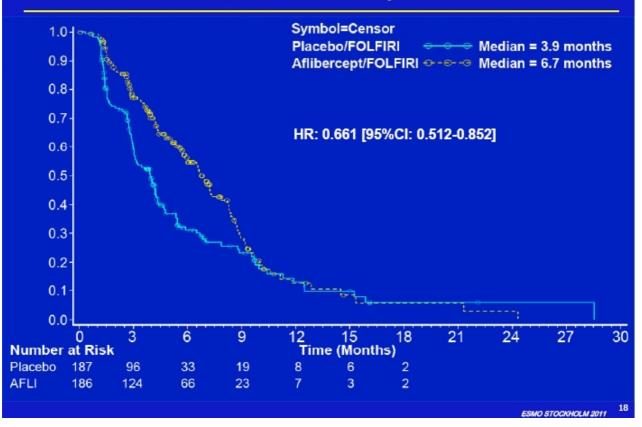
#### Progression Free Survival, Patients with or without Prior Treatment with Bevacizumab - ITT Population

	Placebo/ FOLFIRI Median (mos) N = 614	Aflibercept/FOLFIRI Median (mos) N = 612	P value for interaction
All Patients	4.7	6.9	
Prior BEV			
No	5.4	6.9	
Yes	3.9	6.7	0.6954

Interaction between "treatment arm" and "prior bevacizumab" factor was **not** significant at the 2-sided 10% level (p = 0.6954).

Improvement in PFS was consistent regardless of prior treatment with bevacizumab

#### Progression Free Survival, Patients with Prior Treatment with Bevacizumab - ITT Population



### Safety – Anti-VEGF Associated Events Overall Population

Safety population, % of patients	Placebo/FOLFIRI N = 605		Aflibercept/FOLFIRI N = 611	
Grouped Term, PT	All Grade	Grade 3/4	All Grade	Grade 3/4
Proteinuria*	40.7	1.2	62.2	7.9
Hypertension	10.7	1.5	41.4	19.3
Haemorrhage	19.0	1.7	37.8	2.9
Epistaxis	7.4	0	27.7	0.2
Gl origin	5.1	1.0	10.0	2.0
Dysphonia (PT)	3.3	0	25.4	0.5
Headache (PT)	8.8	0.3	22.3	1.6
Venous thromboembolic event	7.3	6.3	9.3	7.9
Pulmonary embolism	3.5	3.5	4.7	4.7
Arterial thromboembolic event	1.5	0.5	2.6	1.8
Fistula	0.5	0.2	1.5	0.3
Compromized wound healing	0.8	0	0.5	0.3
GI perforation	0.5	0.3	0.5	0.5

\*Systematic pre-dosing urine spot urinalysis

## Safety – Anti-VEGF Associated Events By Prior Treatment with Bevacizumab

	Patients Receiving Aflibercept			
Safety population, % of patients	No prior bevacizumab N =424		Prior bevacizumab N =187	
Grouped Term, PT	All Grade	Grade 3/4	All Grade	Grade 3/4
Proteinuria*	62.5		61.5	
Hypertension	42.2	20.5	39.6	19.9
Haemorrhage	37.3	2.8	39.0	3.2
Epistaxis	26.4	0.2	30.5	0
GI origin	9.9	1.7	10.2	2.7
Dysphonia (PT)	27.8	0.5	19.8	0.5
Headache (PT)	23.1	1.9	20.3	1.1
Venous thromboembolic event	9.0	7.8	10.2	8.0
Pulmonary embolism	5.4	5.4	2.7	2.7
Arterial thromboembolic event	2.4	1.7	3.2	2.1
Fistula	1.9	0.5	0.5	0
Compromized wound healing	0.2	0.2	1.1	0.5
GI perforation	0.7	0.7	0	0
*Systematic pre-dosing urine spot ur	inalysis			ESMO STOCKHOLM 2

### Conclusions

Adding aflibercept to FOLFIRI in mCRC patients previously treated with oxaliplatin based regimen resulted in OS and PFS benefits that are both statistically significant and

clinically meaningful (ESMO/WCGC 2011, Barcelona, Abstract O-0024):

- OS: HR=0.817 [95.34%Cl, 0.713-0.937], p = 0.0032

- PFS: HR=0.758 [99.99%CI, 0.578-0.995], p=0.00007

Pre-planned subgroup analyses supported consistency and robustness of the efficacy results across all domains, including prior treatment with bevacizumab.

Prior treatment with bevacizumab does not appear to significantly impact the safety profile of aflibercept

# Acknowledgements

#### Thank you to all patients, their families and all the investigators who participated:

Argentina	Chile (cont'd)	Italy (cont'd)	Romania (cont'd)	Spain (cont'd)
*Batagelj E	* Loredo E	* Gozza A	* Mihailov A	* Bellmunt J
*Escudero M	* Barajas O	* Aglietta M	* Curca R	* Cantos B
* Costanzo M.V Australia	Czeck Republic	* Frustaci S	* Volovat C	* Merino S
* Shannon J	* Lakomy R	* Maiello E	* lorga P	Sweden
* Parnis F	* Kiss I	* Santoro A	Russia	* Glimelius B
* McKendrick J	* Prausova J	Netherlands	* Tiulandin S	* Karimi M
* Marx G	Denmark	* Van der Velden A	* Biakhov M	* Flygare P
* Desai J		* Kok T		riygarer
*Ng S	* Pfeiffer P	* Erdkamp F	* Moiseyenko V * Roman L	Turkey
* Van Hazel G	* Yilmaz M	* Leeksma O.C		* Buyukberber S
	Estonia	* Ten Tije A.J	* Gorbunova V	
Austria * Scheithauer w	* Leppik K	New Zealand	* Orlova R	* Oksuzoglu B * Abali H
Belgium	<ul> <li>Jõgi T</li> </ul>	* Thompson P		Abaii n
* Peeters M	France	* Jeffery M	South Africa	10
* Van Laethem JL	* Metges JP	Norway	* Ruff P	Ukraine
* Van Cutsem E	* Faroux R	* Guren T	* Slabber C FS	* Vinnik Y
* Humblet Y		* Sorbye H	* Raats J	* Basheyev V
* Delaunoit T	Germany	* Birkemeyer E.M	* Mall R	* Bondarenko I
* d'Haens G	* Schmoll HJ	Poland	* Malan J	* Datsenko O
* Hendlisz A	* Meiler J	* Filipczyk-Cisarz E	* Bouwer J	
Brazil	* Welslau M		* Pirjol A	United Kingdom
* Cubero D	* Kroning H	* Wojcik E		* Samuel L
"Vinholes,J	* Karthaus M	* Dowgier-Witczak I	South Korea	* Valle J
*Oliveira M	Greece	* Zander I	* Kim S Y	* Glynne-Jones R
*Jobim De Azevedo S	* Georgoulias V	* Slomian G	* Park Y S	* Bridgewater J
*Prolla G	* Samantas E	* Koralewski P	* Oh D Y	* Cunningham D
*Hoff P *Azevedo F	* Kalofonos H		* Kim T W	* Ross P
"Vieira F	* Papakostas P	Puerto Rico	* Shin S J	* Propper D
Chile	* Efremidis A	* Baez-Diaz L	Spain	* Ferry D
* Villanueva L	Italy	Romania	* Tabernero J	* Hickish T
* Orlandi F	* Di Bartolomeo M	* Gutulescu N	* Lopez G	
* Vogel C	* Zampino M	* Stanculeanu D	* Gravalos C	22
			Ciavaos C	ESMO STOCKHOLM 2011

## Acknowledgements

#### Thank you to all patients, their families and all the investigators who participated:

United States

\* Radford J
\* Atkins, J
\* Polikoff J
\* Hantel A
\* Gross H
\* Julian T
\* Guarino M
\* Fuloria J
\* Kirshner J
\* Wade J
\* Filynn P
\* Reiling R
\* Salmon S
\* George T
\* Mitchell E

\* Mitchell E \* Robin E

- \* Choksi J
- \* Resta R
- \* d'Andre S
- \* Lee F.C
- \* Sigal D \* Birhiray R
- \* Stella P
- \* Wallmark J

NSABP, M. Guarino for US investigators coordination

United States (cont'd)

\* Gousse R

\* Geils Jr G

\* Armas A

\* Weiner R

\* Nadeem A \* Skinner W

\* Haghighat P

\* Fehrenbacher L \* Del Prete S

\* Daugherty J.P

\* Manges R

\* Shearer H

\* Ghraowi M.A

\* Fink M

\* Lin E

\* Wong L \* Pandit L

\* Vrindavanam N

\* Van Veldhuizen P \* Thomas A \* Cosgriff T

\* Charu V

Disclosure This study (NC

This study (NCT00561470) was funded by sanofi. Aflibercept is being developed in oncology in a partnership between Regeneron and sanofi.